

United States Regulatory Strategy

Fictional Catheter Introducer Sheath

FICTIONAL DEMONSTRATION REPORT

This fictional catheter introducer example demonstrates a regulatory pathway, an evidence plan and assigned next steps. It was prepared with a Panabistics candidate reporting workflow and does not represent the currently deployed release. Inputs are independently authored. No real-device testing, FDA clearance or regulatory sign-off is established. Actual submissions require current requirements, confirmed device details and verified supporting evidence.

Item	Current profile fact
Device profile	portal-synthetic-ci01-regression-project
Legal manufacturer	Synthetic Example Medical LLC
Jurisdiction	United States
Strategy version	0.1.0-us-catheter-introducer-review-mvp-issue48-profile-fidelity-full-detail-2
Ruleset version	review-us-catheter-introducer-issue48-profile-fidelity-full-detail-2
Assessment status	Partial planning result; no completed compliance or test finding
Regulatory review status	No dated human regulatory sign-off is recorded
Detailed planning	20 modules and 104 owned planning records

Strategy purpose and scope

For CI-01 Independent Method Regression Sheath, retain the supplied device boundary and use Class II / 21 CFR 870.1340 / provisional DYB with Traditional 510(k) as the working U.S. planning position. Proposed sterilization method: Electron-beam irradiation. The evidence plan covers the actual dimensional/mechanical, use-related, biological, sterility and packaging/shelf-life questions. No additional kit component, coating, predicate, test result, validated process, exemption or FDA clearance is established. All software roles are explicitly absent; other technology applicability follows its own supplied presence fields. The output remains a partial profile-driven candidate assessment requiring final configuration, current-source, evidence and release review.

The case-specific conclusions, rationale, evidence requests, actions and questions below come from the same structured assessment object. The renderer does not expand the device boundary or add another case's analysis. The detailed plans define profile-specific work, outputs, owners, prerequisites and decision criteria. Evidence presence in an intake is not verification of supporting document contents.

Supplied device profile

Item	Current profile fact
Device boundary	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Intended use	Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access.
Indications for use	Fictional local regression input; no clinical claim.
Intended users	Trained healthcare professionals
Patient population	Adults only; pediatric use excluded.
Use environment	Clinical setting; home use excluded.
Patient contact	Present
Contact duration	Unknown / not supplied
Supplied sterile	Present
Proposed sterilization method	Electron-beam irradiation
Single use	Present
Power	Absent
Connectivity	Absent
Cloud	Absent

Report navigation

Each module link opens its assessment and detailed planning records. The evidence and responsibility index at the end links back to the individual work records.

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01 Device Scope and Regulatory Boundary

Applicability: applicable | Confidence: medium

Current regulatory position

The assessed boundary is the supplied description for CI-01 Independent Method Regression Sheath: Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.

Rationale

Intended use: Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access. Intended users: Trained healthcare professionals. Patient population: Adults only; pediatric use excluded. Use environment: Clinical setting; home use excluded. These are profile-owned statements, not independently verified evidence. No additional component, coating, anatomy, or performance claim is supplied by the rules.

Open questions

- Are final configuration, materials, dimensions and separately supplied compatible devices controlled?

Required evidence

- Controlled configuration, component list, intended-use statement and exclusions for the final marketed device. [device scope]

Recommended actions

- Freeze the marketed device boundary and reconcile the structured intake with its narrative before predicate screening. [high]

Controlled device boundary

The assessment begins with the actual supplied boundary: Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. The intended-use statement is Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access. The planning record must distinguish the sheath and hub from separately supplied compatible equipment. An interface can require compatibility evidence without turning that separate equipment into a supplied component. The component list, drawings, purchasing specifications and labeling must use the same distinction.

A strategy can establish the questions and evidence needed to freeze a design before it has a completed verification file. It cannot close a configuration decision by filling missing dimensions, materials or claims with another device's facts. The following controls define the records needed to turn the present intake into a submission baseline. Each record should identify a revision, an accountable function and the changes that require reassessment.

Device and component boundary

Planning record SCP-01. Prevent the submission and test program from evaluating a different configuration from the one intended for marketing.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Create the marketed component list and distinguish supplied components, separate compatible equipment and excluded features. 2. Link each included component to drawings, specifications and the intended-use contribution; resolve conflicting descriptions before testing. 3. Check that all submission-facing descriptions use the same boundary and retain a dated change history.
Evidence output	Controlled device description and component applicability register.
Decision criteria	Every marketed element is identified and justified; no excluded valve, dilator, coating or additional kit component is silently introduced.
Responsible	Design engineering and regulatory affairs
Prerequisites	No separate planning prerequisite
Evidence status	Planned work; supporting records have not been verified
Source references	21-CFR-870.1340

Configuration and dimensional baseline

Planning record SCP-02. Define which configurations the future evidence must cover, without assigning unsupported nominal sizes or tolerances.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. List proposed models, sheath lengths, internal and external dimensions and compatible interfaces using the design inputs. 2. Record the function and risk affected by each difference; identify potential worst cases for individual tests. 3. Reconcile the variant list with catalogue numbers, test-article identification and labeling before design freeze.
Evidence output	Revision-controlled configuration and dimensional matrix.
Decision criteria	Configurations are reproducible from approved drawings; any evidence-family grouping has a written rationale rather than a single convenient test article.
Responsible	Design engineering
Prerequisites	SCP-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH

Intended use and indication consistency

Planning record SCP-03. Keep the clinical purpose, anatomical scope and limitations consistent across the profile, predicate comparison and labeling.

Profile basis	Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access. Indications: Fictional local regression input; no clinical claim.
Work to perform	1. Separate the intended purpose from proposed indications and from unsupported performance or clinical claims. 2. Review every statement for changes in anatomy, access route, user, duration or patient population. 3. Resolve ambiguous wording with an owned decision and propagate the approved statement to the submission and IFU.
Evidence output	Intended-use and indication master with approved exclusions.
Decision criteria	The final text describes one controlled clinical purpose; differences from a prospective predicate are visible and evaluated.
Responsible	Regulatory affairs and clinical representative
Prerequisites	SCP-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

Users patients and use environment

Planning record SCP-04. Define the actual use conditions that human factors, simulated-use and labeling work will evaluate.

Profile basis	Users: Trained healthcare professionals. Population: Adults only; pediatric use excluded.. Environment: Clinical setting; home use excluded..
Work to perform	1. Record relevant professional roles, training assumptions, procedure context and environmental constraints. 2. Retain excluded populations and settings explicitly; identify any proposed expansion as a separate change. 3. Use those facts to choose representative tasks and test conditions without adding pediatric or home-use scenarios as claimed indications.
Evidence output	Use specification linked to the intended-purpose master.
Decision criteria	Every claimed setting and population is covered; exclusions remain consistent and any needed off-label misuse analysis is labeled as risk analysis.
Responsible	Clinical and human factors functions

Prerequisites	SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE-CONTENT

Patient contact and material definition

Planning record SCP-05. Provide the factual contact map needed for a defensible biological evaluation.

Profile basis	Contact: Not supplied. Duration: Not supplied. Materials: Not supplied.
Work to perform	1. Identify every patient-contacting surface and any indirect exposure through the final finished device. 2. Record contact route and duration using the actual procedure and repeated-use assumptions, not the device name alone. 3. Capture material grades, additives, manufacturing residues and final processing that can affect biological evaluation.
Evidence output	Contact and finished-device material inventory.
Decision criteria	A biological evaluation can trace each relevant exposure to a specified material and process; unresolved contact duration remains an open decision.
Responsible	Materials engineering and biological safety
Prerequisites	SCP-01, SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BIOCOMP

Claim and limitation register

Planning record SCP-06. Prevent planned performance from being promoted to an established result.

Profile basis	No detailed performance or labeling claim supplied
Work to perform	1. List each proposed claim and its intended wording in marketing, labeling and the submission. 2. Assign the evidence needed and define what is still a hypothesis or proposed design requirement. 3. Restrict release wording to the claims supported by the final evidence and evaluate changed claims through change control.
Evidence output	Claim-to-evidence register with proposed supported and withheld wording.
Decision criteria	No clearance, validation, non-pyrogenicity, shelf-life or superior-performance claim is asserted from an intake flag alone.
Responsible	Regulatory affairs and design engineering

Prerequisites	SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-BENCH

Regulatory references

- 21-CFR-870.1340 | Catheter introducer classification | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870/subpart-B/section-870.1340>
- FDA-DYB | FDA product classification record DYB | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB> | Working code; verify the complete current record and final configuration before use.
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-HFE-CONTENT | FDA human factors submission content guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions> | Final guidance May 2026; apply its risk-based content framework with the FDA human factors engineering guidance.
- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>

02 Product Classification

Applicability: applicable | Confidence: medium

Current regulatory position

Working classification is Class II catheter introducer under 21 CFR 870.1340; DYB is the provisional product-code position, subject to final device-definition and current FDA-record review.

Rationale

The regulation identifies a sheath used to facilitate catheter placement through skin into a vein or artery and classifies that generic type as Class II. The profile fits the bounded family for planning; this is not an FDA classification determination, exemption analysis, or confirmation of every marketed component.

Open questions

- Does the final marketed device remain within the catheter-introducer definition and DYB scope?

Required evidence

- Final intended use and configuration mapped to the regulation and the current complete FDA product-code record. [classification]

Recommended actions

- Confirm product-code fit and document any exemption limitations after design inputs are frozen. [high]

Classification decision record

The current working classification is bounded by the sheath function in 21 CFR 870.1340. DYB remains a product-code hypothesis requiring the complete current FDA record and the final marketed configuration. Product classification is distinct from a predicate choice, an exemption decision and a statement that the device has been cleared. A kit, added therapeutic function or materially different intended purpose may require a different analysis even when the word introducer remains in its name.

The classification record should capture the rule language considered, the profile facts supporting the match, alternatives screened out and the reviewer responsible for the decision. Unknown design attributes should be tracked where they could change the result. The engine rejects conflicting supplied class, regulation or product-code values in this bounded branch; that rejection is a request to reconcile the input, not an automated reassignment to a different class.

Regulation definition mapping

Planning record CLS-01. Show why the actual sheath function fits the working generic device definition.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. Intended use: Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access.
Work to perform	1. Map the controlled intended use and sheath function to 21 CFR 870.1340. 2. Identify technological or functional features that may move the final product outside that definition. 3. Retain the dated source and the reviewed configuration in the classification record.
Evidence output	Classification rationale tied to the final profile revision.
Decision criteria	The mapping is complete and contradictory functions are resolved; Class II is a working category, not a clearance or exemption statement.
Responsible	Regulatory affairs

Prerequisites	SCP-01, SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	21-CFR-870.1340

Current FDA product code review

Planning record CLS-02. Confirm the exact code and current regulatory metadata before using it in a submission.

Profile basis	DYB is provisional in the bounded assessment; the complete live product-code record is not certified here.
Work to perform	1. Retrieve and retain the complete official product-code record, including submission type, exemptions and any limitations. 2. Compare the final intended purpose and configuration against the record, rather than relying on a search excerpt. 3. Record the decision, source date and unresolved differences; reassess if the marketed boundary changes.
Evidence output	Current FDA product-code decision and evidence of the record checked.
Decision criteria	The chosen code fits the controlled device and all relevant record conditions are addressed; missing metadata blocks closure.
Responsible	Regulatory affairs
Prerequisites	CLS-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-DYB

Alternative scope and combination checks

Planning record CLS-03. Detect when a proposed feature changes the classification question rather than simply expanding a component list.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Screen added drug, biological, active, implantable or therapeutic functions only if they are proposed for the actual device. 2. Distinguish compatible equipment from an integrated or supplied system and consider the regulatory consequences of each arrangement. 3. Escalate a genuine boundary uncertainty for a separate classification or FDA interaction decision.
Evidence output	Alternative-scope screening log with conclusions and open questions.
Decision criteria	No excluded feature is treated as present; unresolved material changes are evaluated before proceeding under the working DYB branch.

Responsible	Regulatory affairs and design engineering
Prerequisites	SCP-01
Evidence status	Planned work; supporting records have not been verified
Source references	21-CFR-870.1340, FDA-SE

Regulatory references

- 21-CFR-870.1340 | Catheter introducer classification | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870/subpart-B/section-870.1340>
- FDA-DYB | FDA product classification record DYB | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB> | Working code; verify the complete current record and final configuration before use.
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.

03 Market Authorization Regulatory Pathway

Applicability: applicable | Confidence: medium

Current regulatory position

Traditional 510(k) is the provisional planning baseline. Complete a documented pathway and exemption assessment; use eSTAR when FDA's electronic-submission requirement applies.

Rationale

The bounded Class II planning branch does not establish an exemption, prior clearance, substantial equivalence, or a right to market. The final configuration and sponsor history control the submission-type decision.

Open questions

- Is any exemption or alternative submission type supported for the actual final device and sponsor?

Required evidence

- Documented pathway decision and legally marketed predicate strategy for the final device. [pathway]

Recommended actions

- Confirm the pathway before submission assembly and use the applicable FDA electronic template. [high]

Premarket pathway and decision sequence

Traditional 510(k) is the present planning baseline, subject to current product-code, exemption, sponsor-history and final-configuration review. This is a route to prepare and evaluate, not authorization to market. The plan should first establish the intended use and legally marketed comparator relationship, then determine whether the proposed evidence can answer the relevant safety and effectiveness questions. Unresolved differences may justify FDA interaction or a different route assessment.

eSTAR is the submission format when the applicable electronic-submission requirement applies. Completing template fields does not establish substantial equivalence or replace the supporting evidence. The program must separate administrative readiness, technical readiness and the eventual FDA decision. Submission timing and external expenditures should be based on an owned evidence plan; this strategy does not promise a clearance date or assign an unsupported testing budget.

Submission type and exemption assessment

Planning record PTH-01. Choose the submission route after reviewing the final device and the sponsor's actual regulatory history.

Profile basis	Class II and Traditional 510(k) are provisional planning positions; no existing authorization is established.
Work to perform	1. Review current product-code and exemption conditions with the final intended purpose and technology. 2. Review actual prior clearance and modification history where supplied; do not borrow another sponsor's history. 3. Document why the selected route is appropriate and what unresolved facts could change it.
Evidence output	Premarket pathway decision with sources assumptions and alternatives.
Decision criteria	The decision addresses actual configuration and history; exemption or authorization is never inferred solely from Class II status.
Responsible	Regulatory affairs
Prerequisites	CLS-02, SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-510K, FDA-SE

FDA interaction questions

Planning record PTH-02. Use focused regulatory questions when unresolved differences can change the evidence strategy.

Profile basis	The predicate and complete evidence program remain unselected or unverified.
Work to perform	1. Identify the specific decision that needs feedback and assemble the supporting device description and proposed evidence rationale. 2. Separate questions on pathway, comparison, test design or clinical need so the requested feedback is interpretable. 3. Record feedback and its limitations in the decision register; update the evidence plan instead of treating feedback as clearance.
Evidence output	FDA interaction decision and a question package if justified.
Decision criteria	The interaction has a defined purpose and traceable follow-up; optional feedback is not presented as mandatory for every case.
Responsible	Regulatory affairs and relevant technical function
Prerequisites	CMP-07, TST-12
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-510K, FDA-SE

Electronic submission planning

Planning record PTH-03. Prepare the applicable electronic submission structure and preserve consistency between fields and attachments.

Profile basis	The working route is 510(k); eSTAR applicability must follow the current FDA program requirements.
Work to perform	1. Confirm the applicable current template version, submission type and any allowed exceptions at submission freeze. 2. Create an attachment register and map each field to the controlled profile, comparison or evidence record. 3. Check that every completion indication is supported and that exported attachments match the frozen submission revision.
Evidence output	eSTAR field and attachment plan with a controlled template decision.
Decision criteria	The template is appropriate and internally consistent; template completion does not convert missing evidence into a positive result.
Responsible	Submission coordinator and regulatory affairs
Prerequisites	PTH-01, SUB-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-ESTAR

Readiness and marketing release separation

Planning record PTH-04. Prevent administrative acceptance or payment from being confused with FDA authorization or commercial readiness.

Profile basis	The current assessment is a planning output; no submission acceptance or FDA clearance is supplied.
Work to perform	1. Define separate internal gates for evidence completion, submission authorization, FDA decision and commercial release. 2. Assign who controls each gate and the records needed for closure, including approved labeling and applicable operational obligations. 3. Retain open items and avoid promised clearance dates or claims that registration constitutes approval.
Evidence output	Premarket and commercial release gate register.
Decision criteria	Every external statement corresponds to a documented gate; missing evidence or an absent FDA decision remains explicit.
Responsible	Regulatory affairs and quality assurance
Prerequisites	DEC-01, REG-03, LBL-08
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-510K, FDA-REG-LIST

Regulatory references

- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-ESTAR | FDA eSTAR program | Source URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- 21-CFR-870.1340 | Catheter introducer classification | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870/subpart-B/section-870.1340>
- FDA-DYB | FDA product classification record DYB | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB> | Working code; verify the complete current record and final configuration before use.
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-REG-LIST | Role-specific registration and listing | Source URL: <https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>

04 Comparator Equivalence Strategy

Applicability: applicable | Confidence: medium

Current regulatory position

No primary predicate or substantial-equivalence conclusion is selected by this branch. Conduct a documented predicate search against the final intended use and technological characteristics.

Rationale

A shared product code or a recent clearance cannot by itself establish an appropriate predicate. Compare the actual device boundary, materials, dimensions, interfaces, proposed sterilization method, packaging, claims and risk-relevant differences without importing another device's configuration into this profile.

Open questions

- Which candidate has an appropriate intended-use and technology relationship to the final device?

Required evidence

- Predicate screening record and intended-use/technology comparison, with evidence addressing material differences. [predicate]

Recommended actions

- Select and justify a legally marketed predicate before claiming substantial equivalence. [high]

Predicate screening and comparison

No predicate is selected by this assessment. A useful search first defines the controlled intended use and critical technological characteristics, then screens legally marketed devices using official records and available labeling. Sharing a product code is a search aid. It is not enough to justify the comparison, and a recently cleared device is not automatically the best choice. A public summary can support a screening step while leaving important details unresolved.

The comparison must identify how each difference is addressed by the planned evidence. A separate compatible catheter can affect interface testing without becoming a supplied component. Missing material, dimensional or processing facts should remain gaps in the matrix. Where a difference raises a new safety or effectiveness question, the route and evidence decision must be reconsidered. The final rationale should show the selected predicate relationship and any reference-device role separately.

Search criteria and record retention

Planning record CMP-01. Make the predicate search reproducible and tied to the actual device definition.

Profile basis	Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access. Boundary: Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Define intended-use, anatomy, access-route and technology screening criteria before searching. 2. Use official FDA records and retain search terms, dates, candidate identifiers and accessible source documents. 3. Document exclusions and unresolved evidence so a search result is not mistaken for a selected predicate.
Evidence output	Predicate search protocol and screening log.
Decision criteria	The search can be repeated and candidate inclusion is justified against the controlled intended purpose.
Responsible	Regulatory affairs
Prerequisites	SCP-03, CLS-02
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-DYB

Legally marketed device status

Planning record CMP-02. Establish that any proposed primary predicate has an appropriate legal marketing basis.

Profile basis	No predicate or authorization identifier is supplied by this branch.
Work to perform	1. Verify the candidate's official authorization or other valid marketing basis and current relevant status. 2. Retain the public decision record and available labeling, distinguishing facts from unverified summaries. 3. Resolve missing or contradictory information before assigning the primary predicate role.
Evidence output	Candidate legal-status and source record.
Decision criteria	The intended predicate role has a documented legal basis; absence of contrary information is not a substitute for verification.
Responsible	Regulatory affairs
Prerequisites	CMP-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

Intended use comparison

Planning record CMP-03. Evaluate whether the proposed comparison addresses the actual intended use and proposed indications.

Profile basis	Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access. Indications: Fictional local regression input; no clinical claim.
Work to perform	1. Compare purpose, anatomy, access route, users, patient population and setting line by line. 2. Classify each difference by its potential effect on the regulatory and evidence questions. 3. Document a reasoned conclusion and escalate unresolved intended-use differences rather than smoothing them into generic wording.
Evidence output	Intended-use comparison with source-linked differences.
Decision criteria	The selected relationship is supported; expanded anatomy or populations require an explicit evidence/pathway decision.
Responsible	Regulatory affairs and clinical representative
Prerequisites	CMP-02, SCP-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

Technology and component comparison

Planning record CMP-04. Link differences in the final sheath and hub to specific verification questions.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. Material information: Not supplied
Work to perform	1. Compare dimensions, construction, contact materials, interfaces and operating principle where documented. 2. Distinguish facts established by source documents from details not publicly available. 3. Map differences to risk, bench, biological, sterilization, packaging and labeling work; retain unsupported comparisons as gaps.
Evidence output	Technological-characteristics comparison matrix.
Decision criteria	Each material difference has an evidence rationale and owner; no valve, coating or supplied dilator is assumed to match.
Responsible	Design engineering and regulatory affairs
Prerequisites	SCP-02, SCP-05, CMP-02

Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-BENCH

Processing and biological differences

Planning record CMP-05. Consider the finished-device consequences of materials and processing instead of relying only on nominal material names.

Profile basis	Materials: Not supplied. Proposed sterilization: Electron-beam irradiation.
Work to perform	1. Compare documented finished-device materials, processing, proposed sterilization, contact route and duration. 2. Identify differences that can affect chemical exposure, physical integrity, packaging or shelf-life evidence. 3. Assign the additional evaluation needed and explain why any proposed evidence bridge is justified.
Evidence output	Processing and biological difference assessment.
Decision criteria	The evidence plan addresses the finished device; a shared material designation or proposed method does not establish biological equivalence.
Responsible	Biological safety and sterilization functions
Prerequisites	SCP-05, CMP-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BIOCOMP, FDA-STERILITY, FDA-SE

Performance question mapping

Planning record CMP-06. Show how the planned tests address differences relevant to safety and effectiveness.

Profile basis	The final dimensions, detailed performance claims and completed test reports are not verified by this profile assessment.
Work to perform	1. Create a question for each relevant performance difference and link it to a risk or design requirement. 2. Choose a test or justified evidence argument capable of resolving that question and identify representative conditions. 3. Keep acceptance criteria and missing comparison data visible until approved; do not claim successful equivalence before the evidence is evaluated.
Evidence output	Difference-to-evidence traceability matrix.
Decision criteria	Every relevant difference has a closure route; unresolved questions prevent a positive substantial-equivalence conclusion.
Responsible	Design engineering and regulatory affairs

Prerequisites	CMP-04, TST-01, TST-12
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-BENCH

Predicate selection decision

Planning record CMP-07. Record an owned selection rather than an automatic code-based assignment.

Profile basis	This branch has selected no primary predicate and reached no substantial-equivalence conclusion.
Work to perform	1. Review intended-use and technology comparisons together with legal status and evidence availability. 2. Document why the selected candidate supports the proposed route and why alternatives were not chosen. 3. Record unresolved questions and any separate reference-device role; obtain required internal authorization before submission assembly.
Evidence output	Predicate-selection memorandum with the comparison and evidence rationale.
Decision criteria	The selection follows the applicable FDA framework and the final configuration; incompatible fragments from different devices do not replace a justified primary relationship.
Responsible	Regulatory affairs
Prerequisites	CMP-03, CMP-05, CMP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

Regulatory references

- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-ESTAR | FDA eSTAR program | Source URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-DYB | FDA product classification record DYB | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB> | Working code; verify the complete current record and final configuration before use.

- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>

05 Regulatory Requirements

Applicability: applicable | Confidence: medium

Current regulatory position

Maintain a U.S. requirements register covering premarket pathway, labeling, quality systems, registration/listing and postmarket obligations, with device-specific applicability decisions.

Rationale

The planning category does not resolve sponsor roles, exemptions, final labeling, or completed compliance evidence. Each applicable requirement needs a source, owner, deliverable and approval status; no compliance finding is made from an intake flag alone.

Required evidence

- Source-linked requirements/applicability register for the final manufacturer, configuration and market-entry plan. [regulatory requirements]

Recommended actions

- Approve the requirements register and assign owners before submission freeze. [high]

Requirements and applicability register

The requirements register links legal obligations and regulatory recommendations to the actual manufacturer roles, device configuration and stage of market entry. Binding regulations, FDA guidance and voluntary standards should be identified separately. A cited guidance is not automatically a legal requirement, and a recognized standard is not automatically applicable in full. The register should record the reason for applicability, the implementation record and the accountable owner.

For this profile, the immediate decisions concern the premarket route, final labeling, quality-system controls and evidence supporting sterile single-use vascular access. Establishment roles, listing, UDI and postmarket operations depend on the final commercial arrangement. These obligations should

be planned early, while their actual applicability and completion remain separate decisions. A completed checklist field cannot substitute for the underlying controlled record.

Requirement source and applicability

Planning record REQ-01. Create one controlled register that distinguishes mandatory obligations from recommendations and chosen evidence approaches.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. Manufacturer: Synthetic Example Medical LLC
Work to perform	1. Identify the relevant law, guidance or standard and record its issuing authority and current version. 2. Map the requirement to actual device and establishment facts, documenting applicability, exceptions and unresolved conditions. 3. Assign an implementation record and owner; keep the register under change control.
Evidence output	Source-linked U.S. requirements and applicability register.
Decision criteria	Each row has a defensible source, applicability rationale and implementation route; uncertainty is not represented as completed compliance.
Responsible	Regulatory affairs and quality assurance
Prerequisites	CLS-02, SCP-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-510K, FDA-QMSR, FDA-SYMBOLS

Premarket evidence and claim control

Planning record REQ-02. Connect the planned evidence program to the claims that will appear in the submission and labeling.

Profile basis	No detailed performance or labeling claim supplied
Work to perform	1. Map proposed claims to comparison questions, risk controls and supporting evidence outputs. 2. Define the reviewer and decision criteria for each claim rather than relying on a favorable test summary alone. 3. Withhold unsupported wording and ensure changes trigger the appropriate evidence and regulatory reassessment.
Evidence output	Claim and requirement evidence register with closure status.
Decision criteria	A claim is supported by the correct final configuration and evaluated evidence; no invented test or clearance result appears in release wording.
Responsible	Regulatory affairs and design engineering
Prerequisites	SCP-06, CMP-06

Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-BENCH

Operational obligations and calendars

Planning record REQ-03. Prepare role-specific obligations that continue after premarket evidence preparation.

Profile basis	Actual establishment activities, labeler role and distribution arrangements remain to be confirmed.
Work to perform	1. Identify who will manufacture, sterilize, label, import and distribute the final device. 2. Map registration/listing, identification and reporting duties to those roles using current official sources. 3. Define responsible backups, record retention and calendar controls; verify applicable periods before operational release.
Evidence output	Role-based obligations calendar and operating responsibility matrix.
Decision criteria	Every applicable duty has an accountable entity and a current-source decision; no fee, registration or identifier is invented.
Responsible	Quality assurance and regulatory operations
Prerequisites	REG-01, LBL-06, PMS-02
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-REG-LIST, 21-CFR-830.300, 21-CFR-803.50

Evidence closure and exceptions

Planning record REQ-04. Keep unresolved requirements visible and avoid closing them with generic statements.

Profile basis	The assessment contains planning requests and does not independently verify uploaded technical-file contents.
Work to perform	1. Define what evidence demonstrates closure and who can authorize an exception or alternate approach. 2. Record the evidence revision, review conclusion, deviation and residual open questions for each applicable requirement. 3. Reconcile the register before submission and commercial release; escalate missing evidence that changes safety, effectiveness or pathway decisions.
Evidence output	Requirement closure and exception log.
Decision criteria	Closure is traceable to a reviewed record; exceptions have a rationale and authorization appropriate to their consequence.

Responsible	Quality assurance and regulatory affairs
Prerequisites	REQ-01, DEC-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-QMSR

Regulatory references

- 21-CFR-870.1340 | Catheter introducer classification | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870/subpart-B/section-870.1340>
- FDA-DYB | FDA product classification record DYB | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB> | Working code; verify the complete current record and final configuration before use.
- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
- FDA-REG-LIST | Role-specific registration and listing | Source URL: <https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>
- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-SYMBOLS | FDA use of symbols in labeling | Source URL: <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling> | FDA permits symbols with adjacent explanation and conditionally permits stand-alone standardized symbols.
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- 21-CFR-830.300 | UDI data submission applicability | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-830/subpart-E/section-830.300> | Current eCFR text retrieved; assess labeler/model/UDI applicability and exceptions rather than inventing identifiers.
- 21-CFR-803.50 | Manufacturer medical device reporting | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803/subpart-E/section-803.50> | Current text retrieved. Includes qualifying death/serious injury and recurrent-

malfunction reporting within 30 calendar days; assess other applicable reporting provisions separately.

06 Guidance Regulatory Reference Applicability

Applicability: applicable | Confidence: medium

Current regulatory position

Assess FDA 510(k)/eSTAR, biological evaluation and sterile-device guidance against the final profile. Component- or coating-specific guidance is conditional on the actual final configuration, not asserted as applicable by this branch.

Rationale

The device is supplied sterile with patient contact stated in the profile. Proposed sterilization method: Electron-beam irradiation. Contact category, duration, materials, claims and any additional component functionality remain input-dependent.

Required evidence

- Guidance applicability matrix documenting scope, exclusions, relevant recommendations and justified deviations. [guidance]

Recommended actions

- Recheck the current relevant guidance and final device-specific applicability before approving protocols. [high]

Guidance scope and evidence decisions

Guidance selection should follow the actual regulatory question. The FDA bench-report guidance addresses how bench information is documented; it does not cover the separate biological, sterilization, human factors or software evaluations. The biological evaluation and sterile-device guidance address different evidence questions. A single list of document titles is therefore insufficient: the program needs an applicability rationale and a record of how each relevant recommendation is addressed.

For the supplied proposed method, Electron-beam irradiation, select the appropriate sterility evidence framework and preserve uncertainty in any unresolved process decision. For the supplied users and environment, determine the human factors submission content using the current May 2026 risk-based guidance and its engineering companion. A component-specific document should not be treated as applicable when that component is excluded from the marketed boundary.

Guidance applicability and currency

Planning record GDN-01. Keep a reviewable connection between current FDA recommendations and the final device's evidence program.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Record each official guidance, its date, final or draft status and the question it addresses. 2. State why it applies, applies in part or does not apply to the marketed configuration; record alternative approaches where justified. 3. Review the register at design, evidence and submission freezes and document changes in the plan.
Evidence output	Guidance applicability and currency register.
Decision criteria	Drafts are identified as drafts; current recommendations and approved alternatives are traceable to planned outputs rather than generic statements.
Responsible	Regulatory affairs
Prerequisites	REQ-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-BENCH, FDA-HFE-CONTENT

Bench report scope

Planning record GDN-02. Use the bench guidance for the information it actually covers without treating it as a universal validation standard.

Profile basis	Dimensional, mechanical, interface and simulated-use questions concern the final sheath and hub.
Work to perform	1. Map bench questions to controlled protocols, summaries and final reports with test-article identification. 2. Separate biological evaluation, sterilization, usability and any other specialized evidence into their own workstreams. 3. Document the chosen reporting approach and any deviations that affect interpretation of the result.
Evidence output	Bench documentation plan and discipline-specific evidence index.
Decision criteria	The evidence categories are appropriate and complete; a bench summary is not used to close an unrelated biological or sterilization question.
Responsible	Verification engineering and regulatory affairs
Prerequisites	TST-12
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH

Human factors content decision

Planning record GDN-03. Align submission content to the actual use-related risks and current FDA framework.

Profile basis	Users: Trained healthcare professionals. Environment: Clinical setting; home use excluded..
Work to perform	1. Evaluate the use-related risk analysis and identify the applicable human factors content category under current FDA recommendations. 2. Document the design history, differences and rationale supporting the category; identify required supporting evaluations. 3. Reconcile the submission content with the final user interface and instructions rather than assuming professional use removes the need for analysis.
Evidence output	Human factors content-category rationale and supporting record list.
Decision criteria	The category follows the actual design and risks; no category or completed validation is invented by this report.
Responsible	Human factors and regulatory affairs
Prerequisites	HFE-02, HFE-05
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE-CONTENT, FDA-HFE

Specialized evidence boundaries

Planning record GDN-04. Prevent a generalized guidance list from obscuring unresolved biological and sterile-device questions.

Profile basis	Contact information: Not supplied. Proposed method: Electron-beam irradiation.
Work to perform	1. Map finished-device biological and sterilization questions to their respective guidance and specialist review. 2. Identify missing contact, processing, packaging or claim facts that change the recommended evidence. 3. Record the decision and supporting rationale, including any justifiable alternative evidence approach.
Evidence output	Specialized-guidance applicability and decision record.
Decision criteria	The chosen evidence addresses actual exposures and processing; unrelated component guidance does not supply missing case facts.
Responsible	Biological safety sterilization and regulatory affairs
Prerequisites	SCP-05, STD-03, STD-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BIOCOMP, FDA-STERILITY

Regulatory references

- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-ESTAR | FDA eSTAR program | Source URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- FDA-HFE-CONTENT | FDA human factors submission content guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions> | Final guidance May 2026; apply its risk-based content framework with the FDA human factors engineering guidance.
- FDA-HFE | FDA human factors engineering guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices> | Companion source identified by FDA; confirm device-specific applicability and current recommendations.

07 Standards Applicability

Applicability: applicable | Confidence: medium

Current regulatory position

Develop a standards matrix for the actual introducer, biological evaluation, proposed sterilization method (Electron-beam irradiation), packaging and risk-management evidence. Plan electron-beam irradiation validation, dose establishment and substantiation, dose mapping, routine process control, and material/package compatibility for the final configuration. No validated dose or process is established by this profile.

Rationale

Identify the appropriate standard scope, exact edition, FDA recognition status and any transition limitations before a declaration of conformity. A standard's title or a supplied intake declaration does not establish conformance or validated performance.

Required evidence

- Controlled matrix of standard identifiers, editions, recognition records, applicability, deviations and associated verification evidence. [standards]

Recommended actions

- Freeze the applicable standards and acceptance criteria with justified deviations before verification. [high]

Standards selection and conformity strategy

The standards matrix should record a designation and edition, why the standard applies, the relevant device or process scope, current FDA recognition and any limitations or transition date. Publisher currency, FDA recognition and demonstrated conformance are different facts. The ISO 11070 publisher metadata identifies a relevant introducer standard, but its exact current FDA recognition record has not been retrieved in this run. That remains an explicit check before a declaration of conformity.

FDA recognition 5-148 covers ISO 15223-1 fourth edition 2021-07 including its 2025 amendment. The FDA record states the prior 5-134 recognition transition ends December 17 2028. That verified metadata does not establish that every symbol is appropriate to this device or that a final label is compliant. For the other candidate standards below, exact editions, recognition and scope must be recorded before they are used as a conformity basis. No proprietary standard clauses are embedded in this strategy.

Edition and FDA recognition control

Planning record STD-01. Establish the exact standards basis for testing and any eventual declaration of conformity.

Profile basis	This assessment proposes a standards workstream and does not certify conformance.
Work to perform	- For each candidate designation, retain the current FDA recognition number, supplementary information sheet, recognized extent and transition conditions. - Record the exact edition used by the laboratory and how deviations or excluded clauses affect the evidence. - Review changes at protocol approval and submission freeze; block unsupported declarations until the conformity evidence is complete.
Evidence output	Controlled standards and recognition matrix with source dates.
Decision criteria	The exact tested edition and recognition basis agree; unresolved scope or deviations are disclosed and assessed rather than hidden.

Responsible	Regulatory affairs and verification engineering
Prerequisites	REQ-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STANDARDS, FDA-STANDARDS-SEARCH

Introducer product standard scope

Planning record STD-02. Use product-specific standards without treating excluded needles, dilators or guidewires as supplied components.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Evaluate ISO 11070:2014 and its 2018 amendment against the actual sheath and hub using authorized access to the standard. 2. Determine the applicable tests and exclusions, including final construction and interface functions; verify the current FDA recognition separately. 3. Document how the chosen product-standard evidence relates to design requirements, risks and any supplemental testing.
Evidence output	Introducer-standard applicability and protocol mapping.
Decision criteria	Only applicable device features are evaluated; product-standard scope, exact editions and missing recognition facts are explicit.
Responsible	Verification engineering and regulatory affairs
Prerequisites	SCP-01, SCP-02, STD-01
Evidence status	Planned work; supporting records have not been verified
Source references	ISO-11070-METADATA, FDA-STANDARDS-SEARCH, FDA-BENCH

Biological evaluation standards strategy

Planning record STD-03. Choose the biological evaluation framework for the actual finished-device exposures.

Profile basis	Contact: Not supplied. Duration: Not supplied. Materials: Not supplied.
Work to perform	1. Use the FDA biological guidance to determine the contact categorization and questions that need evaluation. 2. Identify relevant ISO 10993-series methods or alternative evidence, with current editions, applicability and recognition recorded. 3. Separate test selection from conclusions; justify existing evidence, chemical characterization or additional testing for each relevant question.
Evidence output	Biological evaluation standards and evidence rationale.

Decision criteria	The plan covers the finished-device exposures and resolves material/process gaps; no endpoint is waived solely because a material name appears familiar.
Responsible	Biological safety
Prerequisites	SCP-05, STD-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BIOCOMP, FDA-STANDARDS-SEARCH

Radiation sterilization standards strategy

Planning record STD-04. Choose a method-specific conformity framework that matches the controlled sterilization decision.

Profile basis	The structured method is electron-beam irradiation; no dose or validated process is established.
Work to perform	1. Evaluate the relevant ISO 11137 series for process development, dose establishment and dosimetry, using exact current editions and FDA recognition metadata. 2. Link the selected framework to the final product family, bioburden, density, loading arrangement and material/package compatibility evidence. 3. Record the process-specific scope, exclusions and evidence to support the declaration; do not assume a nominal dose is validated.
Evidence output	Sterilization standards applicability and validation evidence matrix.
Decision criteria	The process and standard scope match; validation parameters and supporting results must come from controlled evidence, never from the intake flag.
Responsible	Sterilization function and regulatory affairs
Prerequisites	STD-01, SCP-05
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STERILITY, FDA-STANDARDS-SEARCH

Microbiological method selection

Planning record STD-05. Ensure the microbiological evidence is appropriate to the product and selected sterile-device process.

Profile basis	Supplied-sterile status is explicit; microbiological test reports have not been verified.
Work to perform	1. Evaluate relevant ISO 11737 methods and their suitability for the actual product, recovery approach and process evidence. 2. Define how method suitability, sampling, product grouping and ongoing monitoring support interpretation of the data. 3. Record exact editions, recognition and any justified alternatives alongside the process-specific validation plan.
Evidence output	Microbiological methods and suitability evidence plan.
Decision criteria	Recovery and sampling are justified for the finished device; a negative test alone is not treated as proof of a validated sterilization process.
Responsible	Microbiology and sterilization functions
Prerequisites	STD-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STERILITY, FDA-STANDARDS-SEARCH

Packaging and aging standards strategy

Planning record STD-06. Link the sterile-barrier and shelf-life approach to a defensible test and validation framework.

Profile basis	Not supplied
Work to perform	1. Evaluate relevant ISO 11607 packaging and process-validation frameworks using the final package materials and manufacturing process. 2. Select distribution, integrity, seal and aging methods appropriate to the device/package risks and planned claims. 3. Record current editions, FDA recognition, worst-case choices and evidence limitations before approving protocols.
Evidence output	Packaging-standard and shelf-life method matrix.
Decision criteria	Package integrity, manufacturing processes and aged device performance are covered; a single test method does not establish every shelf-life claim.
Responsible	Packaging engineering and quality assurance
Prerequisites	STD-01, SCP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STERILITY, FDA-BENCH, FDA-STANDARDS-SEARCH

Risk and quality framework mapping

Planning record STD-07. Connect risk-management and quality-system practices to the evidence program without reproducing proprietary clauses.

Profile basis	The current profile is a non-powered patient-contacting sterile single-use sheath and hub.
Work to perform	1. Evaluate ISO 14971 risk-management and the applicable QMSR/ISO 13485 framework with authorized access to the standards. 2. Map company processes and controlled outputs to applicable requirements and to the device's real hazards. 3. Keep risk acceptance, design decisions and process effectiveness review separate from a claim that the report itself demonstrates conformance.
Evidence output	Risk and quality framework applicability mapping.
Decision criteria	Applicable controls have owned records and evidence; no certificate or system-conformance finding is generated from a planning report.
Responsible	Quality assurance and risk management
Prerequisites	STD-01, QMS-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-STANDARDS

Labeling symbol standard and glossary

Planning record STD-08. Use the actual standardized symbols with a current edition decision and device-specific explanations.

Profile basis	The report includes sourced symbol graphics as planning examples; no physical label has been released.
Work to perform	1. Use the verified FDA 5-148 recognition metadata to choose the labeling-symbol edition and document transition considerations. 2. Check each proposed symbol's meaning, reference, adjacent explanatory text or glossary approach, and applicability to final evidence. 3. Retain the artwork source, license notice and release control; assess the final printed symbol and explanation for readability.
Evidence output	Controlled symbol glossary and artwork-source register.
Decision criteria	Symbol meaning, edition and applicability are traceable; a graphic does not establish a sterile claim, issued UDI or label approval.
Responsible	Regulatory affairs and labeling function
Prerequisites	LBL-07, STD-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-15223-5-148, FDA-SYMBOLS, FDA-SYMBOLS-FAQ

Regulatory references

- FDA-STANDARDS | Appropriate use of voluntary consensus standards | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>
- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA-STANDARDS-SEARCH | FDA recognized consensus standards database | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm> | Use the exact edition, recognition number, supplementary information sheet, scope and transition; a search link alone is not verification.
- ISO-11070-METADATA | ISO 11070 public catalogue metadata | Source URL: <https://www.iso.org/standard/63315.html> | 2014 edition with 2018 amendment; publisher metadata checked. Exact current FDA recognition, extent and limitations remain to be verified. No standard clauses are reproduced.
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
- FDA-15223-5-148 | FDA recognition 5-148 for ISO 15223-1 | Source URL: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=46534 | ISO 15223-1 fourth edition 2021-07 including Amendment 1 2025. FDA record checked October 13 2026; prior recognition 5-134 transition ends December 17 2028.
- FDA-SYMBOLS | FDA use of symbols in labeling | Source URL: <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling> | FDA permits symbols with adjacent explanation and conditionally permits stand-alone standardized symbols.
- FDA-SYMBOLS-FAQ | FDA labeling symbols questions and answers | Source URL: <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling-frequently-asked-questions> | FDA explains adjacent text, standardized symbols, glossary content and glossary location.

08 Quality Management System Conformity Assessment

Applicability: applicable | Confidence: medium

Current regulatory position

Plan the finished-device manufacturer's applicable QMSR controls, including design records, suppliers, process validation, product release, change control and post-production feedback.

Rationale

QMSR is the applicable FDA quality-system framework as of its effective date. Proposed sterilization method: Electron-beam irradiation. Sterilization supplier/site, manufacturing sites and completed validations are not inferred; outsourced activities still require manufacturer oversight appropriate to its role.

Open questions

- Which sites and suppliers perform each controlled activity, and what evidence is complete?

Required evidence

- Controlled design/development, supplier, validation, release and change-management records for the final device and manufacturer. [quality system]

Recommended actions

- Confirm manufacturer roles and establish responsibilities for the actual manufacturing and sterilization sites. [high]

Design risk and manufacturing controls

Quality-system planning should use the applicable current QMSR framework and the actual manufacturer roles. The strategy does not establish that a quality system is implemented or certified. For this device, design controls must connect the intended purpose, configuration, patient-contacting materials, sterile-device processing, packaging and labeling to the records needed for verification, validation and transfer. The document titles used by a company can vary; the underlying controlled activities and evidence must remain identifiable.

Outsourced manufacturing, sterilization or testing does not resolve the manufacturer's oversight questions. Agreements, process specifications, change notification, acceptance activities and retained records should define who controls each critical decision. Risk-management records need to distinguish potential hazards from observed failures and should be updated as verification, use-related and postmarket evidence develops. The controls below provide an owned record structure rather than asserting that the hypothetical company has completed these activities.

Design and development plan

Planning record QMS-01. Define responsibilities and decision gates before the evidence program is executed.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Identify the configuration baseline, intended purpose, design stages, accountable functions and required independent review arrangements. 2. Plan links between design inputs, outputs, risk controls, verification, validation, transfer and change control. 3. Define the controlled records and approval authority for each stage, including how unresolved decisions affect progression.
Evidence output	Design and development plan with stage gates and record index.
Decision criteria	Responsibilities and deliverables are coherent with the final device and applicable quality framework; schedule pressure does not override an unresolved safety decision.
Responsible	Design lead and quality assurance
Prerequisites	SCP-01, SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR

Design inputs and outputs

Planning record QMS-02. Translate the intended use and risk controls into measurable design requirements and reproducible specifications.

Profile basis	Intended use: Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access.. Detailed dimensions and materials: Not supplied.
Work to perform	1. Define functional, dimensional, compatibility, biological, sterile-barrier, use and labeling requirements with source and rationale. 2. Link requirements to drawings, materials, process specifications, IFU and acceptance activities. 3. Resolve incomplete or conflicting inputs before selecting test articles and issuing final manufacturing specifications.
Evidence output	Design input and output traceability matrix.
Decision criteria	Every required function or control has a specification and verification route; numerical limits are approved design criteria, not numbers invented by the report.
Responsible	Design engineering
Prerequisites	SCP-02, SCP-05, SCP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-BENCH

Critical supplier and outsourced process control

Planning record QMS-03. Control the effect of supplier and subcontractor activities on the finished device.

Profile basis	Not supplied Proposed process: Electron-beam irradiation
Work to perform	1. Identify suppliers of critical materials, packaging, manufacturing services, sterilization and testing as applicable. 2. Define specifications, qualification evidence, quality agreements, records access, change notification and acceptance responsibilities. 3. Evaluate how supplier or site changes affect the validated product/process family and the evidence supporting final release.
Evidence output	Critical-supplier matrix and outsourced-process control plan.
Decision criteria	Critical activities have documented controls and oversight; an external certificate or supplier statement alone does not establish final-device conformity.
Responsible	Supplier quality and manufacturing
Prerequisites	QMS-02, STD-04, STD-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-STERILITY

Device hazard and risk analysis

Planning record QMS-04. Develop risk questions and controls for the actual sheath and hub rather than importing another device's failure history.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Analyze potential tissue or vessel injury, loss of device integrity, particulate exposure, incompatibility, use error, contamination and loss of sterile-barrier protection where relevant. 2. Document foreseeable sequences, controls and evidence questions, distinguishing hypothetical hazards from observed events. 3. Assign risk acceptability criteria under the manufacturer's process and evaluate residual risks with the completed evidence and intended clinical benefit.
Evidence output	Device-specific risk-management plan and analysis with control verification links.
Decision criteria	Hazards and controls follow the actual boundary; excluded components do not acquire asserted failure modes and no risk score is fabricated.
Responsible	Risk management with design clinical and quality functions
Prerequisites	SCP-01, SCP-04, SCP-05

Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-SE

Verification and validation traceability

Planning record QMS-05. Show how the approved design and risk questions will be resolved by appropriately scoped evidence.

Profile basis	The assessment requests evidence but does not review completed test records.
Work to perform	1. Map each requirement and risk control to a protocol, test article, method and acceptance basis. 2. Distinguish verification of specifications from validation of intended-use needs and selected processes. 3. Retain actual results, deviations, investigation and review conclusions before marking an item closed.
Evidence output	Requirement risk and evidence traceability matrix.
Decision criteria	Coverage is complete and matches the final configuration; a missing or failed result cannot be closed with an unsourced statement of compliance.
Responsible	Verification engineering and quality assurance
Prerequisites	QMS-02, QMS-04, TST-12
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-BENCH

Process validation and transfer

Planning record QMS-06. Establish a controlled transition from approved design to reproducible manufacture and release.

Profile basis	Not supplied Packaging: Not supplied
Work to perform	1. Identify process outputs whose quality cannot be fully assured by subsequent inspection and define the appropriate validation approach. 2. Plan material, assembly, packaging and sterilization controls using the final design and critical process inputs. 3. Define transfer acceptance, training, records, routine monitoring and revalidation triggers for the actual sites and product families.
Evidence output	Design-transfer and critical-process validation plan.
Decision criteria	The transferred process can reproduce the controlled device and package; validation and routine-release evidence remain separate and traceable.
Responsible	Manufacturing packaging sterilization and quality assurance
Prerequisites	QMS-03, TST-08, TST-09

Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-STERILITY

Document records and training controls

Planning record QMS-07. Make the operational record system capable of preserving configuration and decision history.

Profile basis	Manufacturer sites and controlled record systems have not been independently verified.
Work to perform	1. Define document approval, version control, record retention, access and change-history controls appropriate to the actual organization. 2. Identify training and competence needs for design, manufacturing, sterile-device release, complaint handling and regulatory reporting. 3. Verify that superseded documents are controlled and that released lots can be traced to the specifications and decisions applicable at manufacture.
Evidence output	Controlled document record and competence matrix.
Decision criteria	People can identify and use the correct revision, and records support traceability without relying on uncontrolled draft files.
Responsible	Quality assurance
Prerequisites	QMS-01, QMS-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR

Nonconformity CAPA and effectiveness

Planning record QMS-08. Create an evidence-based response to failures and recurring issues during development and commercial operations.

Profile basis	No actual nonconformance or adverse-event history is asserted for this fictional device.
Work to perform	1. Define intake, containment, investigation and disposition routes for development, manufacturing and field nonconformities. 2. Connect corrective action to the underlying cause, risk impact and affected configurations or lots. 3. Set an effectiveness review and feed relevant changes back into design, supplier, validation and postmarket controls.
Evidence output	Nonconformity and CAPA workflow linked to device risk and change control.
Decision criteria	Actions address verified causes and their effectiveness; disposition does not erase evidence gaps or bypass applicable reporting duties.

Responsible	Quality assurance with technical and regulatory owners
Prerequisites	QMS-04, PMS-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-MDR, FDA-RECALL

Regulatory references

- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-MDR | Medical device reporting | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>
- FDA-RECALL | Corrections and removals | Source URL: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>

09 Submission or Technical Documentation Strategy

Applicability: applicable | Confidence: medium

Current regulatory position

Prepare a controlled, source-linked submission structure for device description, indications, predicate comparison, risk-related verification, biological safety, sterility, packaging/shelf life, labeling and administrative material as applicable.

Rationale

The same controlled configuration must appear in the intake, design records, test plans/reports, labeling and submission. This Strategy engine assesses structured profile information; it does not establish that uploaded technical-file contents have been comprehensively reviewed.

Required evidence

- Submission attachment register identifying the configuration/version, evidence owner and completion status of each applicable section. [submission]

Recommended actions

- Reconcile every submission-facing statement and attachment with the controlled profile and actual evidence. [high]

Submission structure and evidence control

The submission should describe one controlled device and make its regulatory argument reviewable. The eSTAR fields and attachments need a common configuration, intended purpose, source date and evidence revision. A populated field is not proof that its supporting record is adequate. Where the profile identifies evidence availability, the submission team must still verify what the record contains and whether it supports the actual marketed device.

Use an attachment register to identify author, revision, intended submission role, referenced sections and unresolved issues. Separate complete reports from summaries and separate technical recommendations from binding requirements. The final assembly review should reconcile claims, predicate comparisons, standards declarations, methods, labeling and administrative information. This Strategy assessment plans those controls; it does not certify that raw uploaded technical-file contents were comprehensively reviewed.

Submission architecture and attachment register

Planning record SUB-01. Create a controlled map of submission fields and supporting records before assembling the final package.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. Intended purpose: Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access.
Work to perform	1. Map the applicable eSTAR sections to the final device description, indication, comparison and evidence categories. 2. Assign attachment names, authors, revisions and cross-references using a consistent record convention. 3. Record missing attachments and planned closure owners; distinguish a planned document from an evaluated completed record.
Evidence output	Submission section and attachment register.
Decision criteria	Each applicable field has a controlled supporting record or an explicit unresolved item; unrelated case material is excluded.
Responsible	Submission coordinator and regulatory affairs
Prerequisites	SCP-01, PTH-01
Evidence status	Planned work; supporting records have not been verified

Source references	FDA-ESTAR, FDA-510K
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Device description and comparison package

Planning record SUB-02. Make the classification and substantial-equivalence argument internally consistent and evidence linked.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Assemble the controlled description, configuration list, intended use and relevant technical specifications. 2. Include the justified predicate relationship and the comparison of intended use and technological characteristics. 3. Identify every material difference and link it to the evidence or regulatory decision that addresses the resulting question.
Evidence output	Device description and predicate comparison attachment set.
Decision criteria	The argument follows the final marketed boundary and the selected route; missing comparison facts remain visible.
Responsible	Regulatory affairs and design engineering
Prerequisites	SCP-02, CMP-07
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

Evidence summaries and complete reports

Planning record SUB-03. Ensure the submission accurately represents the scope and limitations of each evidence category.

Profile basis	Bench biological sterilization packaging and usability records have not been independently verified by this profile assessment.
Work to perform	1. Create concise evidence summaries linked to complete controlled protocols and reports where applicable. 2. Describe test articles, methods, acceptance criteria, results, deviations and conclusions at the appropriate level for each discipline. 3. Reconcile the summaries with underlying reports and retain unresolved limitations that affect interpretation.
Evidence output	Evidence summaries with a complete-report traceability index.
Decision criteria	The summary does not omit a material failure, deviation or limitation and does not claim testing that was not performed.
Responsible	Technical evidence owners and submission coordinator
Prerequisites	TST-12, QMS-05

Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, FDA-BIOCOMP, FDA-STERILITY, FDA-HFE-CONTENT

Standards and conformity statements

Planning record SUB-04. Avoid an unsupported declaration based only on a standards list or supplier statement.

Profile basis	Only labeling-symbol FDA recognition metadata has been specifically verified in this extension; other exact recognition checks remain open.
Work to perform	1. Confirm the exact standard edition, FDA-recognized extent, transition status and applicable tested configuration. 2. Reconcile declarations with actual results, deviations, excluded scope and any alternative evidence. 3. Have the responsible authorized function approve the final statement and retain its supporting evidence.
Evidence output	Reviewed standards declarations and limitations record.
Decision criteria	Every declaration is supported by the correct edition and evidence; unresolved conformance remains a gap rather than a positive assertion.
Responsible	Regulatory affairs and quality assurance
Prerequisites	STD-01, QMS-05
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STANDARDS, FDA-STANDARDS-SEARCH

Administrative and labeling consistency

Planning record SUB-05. Ensure the identity and intended-use records agree across administrative forms and final labeling.

Profile basis	Synthetic Example Medical LLC Proposed indication: Fictional local regression input; no clinical claim.
Work to perform	1. Check the actual applicant, manufacturer, contact roles and authorized administrative declarations. 2. Reconcile model identifiers, intended-use statements and final labeling with the controlled description and evidence. 3. Confirm applicable current submission administrative requirements and payment arrangements through the actual authorized workflow.
Evidence output	Administrative and labeling reconciliation checklist with record references.
Decision criteria	Identity and claims are consistent; the report does not fabricate an applicant authorization, registration number, fee payment or issued identifier.

Responsible	Regulatory operations and labeling function
Prerequisites	LBL-08, REG-01, SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-510K, FDA-ESTAR, FDA-REG-LIST

Submission freeze and response control

Planning record SUB-06. Preserve the exact evidence package submitted and control subsequent responses or changes.

Profile basis	No submission or FDA review result is claimed for this fictional planning case.
Work to perform	1. Record the approved package revision, attachment inventory, final checks and authorization to submit. 2. Retain a reproducible submitted copy and log questions, response owners, deadlines and changed evidence. 3. Assess whether any response change affects claims, comparison, design baseline or supporting validation and reconcile all affected sections.
Evidence output	Submission freeze record and regulatory response change log.
Decision criteria	The submitted version is identifiable and responses remain consistent; an administrative milestone is not treated as clearance.
Responsible	Submission coordinator and regulatory affairs
Prerequisites	SUB-02, SUB-03, SUB-04, SUB-05
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-ESTAR, FDA-SE

Regulatory references

- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-ESTAR | FDA eSTAR program | Source URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final

guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.

- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- FDA-HFE-CONTENT | FDA human factors submission content guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions> | Final guidance May 2026; apply its risk-based content framework with the FDA human factors engineering guidance.
- FDA-STANDARDS | Appropriate use of voluntary consensus standards | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>
- FDA-STANDARDS-SEARCH | FDA recognized consensus standards database | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm> | Use the exact edition, recognition number, supplementary information sheet, scope and transition; a search link alone is not verification.
- FDA-REG-LIST | Role-specific registration and listing | Source URL: <https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>

10 Evidence and Testing Strategy

Applicability: applicable | Confidence: medium

Current regulatory position

Plan risk-linked dimensional/compatibility, mechanical integrity, simulated-use, biological, sterility and packaging/shelf-life verification for the actual device boundary. Plan electron-beam irradiation validation, dose establishment and substantiation, dose mapping, routine process control, and material/package compatibility for the final configuration. No validated dose or process is established by this profile.

Rationale

Test methods, worst-case configurations and acceptance criteria must follow final design inputs, contact category/duration, risk controls, applicable standards and justified predicate differences. Additional component or coating tests are required only where the final configuration makes them relevant. No test result or validated performance is supplied by the rules.

Required evidence

- Dimensional and interface-compatibility verification against the controlled final design. [bench]

- Mechanical and simulated-use evidence addressing the final sheath and interface risks. [bench and simulated use]
- Biological evaluation based on final patient-contacting materials, manufacturing residues and contact duration. [biological safety]
- Electron-beam process validation and routine-control records tied to the final device and packaging; evidence is requested, not assumed to exist. [sterility]
- Sterile-barrier, distribution, aging and shelf-life evidence supporting the actual package and proposed expiry. [packaging and shelf life]

Recommended actions

- Approve a traceable evidence plan before testing; retain missing evidence and unresolved acceptance criteria as open items. [high]

Bench and simulated use evidence

The test program should answer defined design, risk and comparison questions. Protocols need the final device revision, representative test articles, conditioning, method suitability, sample-size rationale, acceptance criteria and deviation handling. A convenient sample set or a familiar test method is not automatically sufficient. Where materials, dimensions, compatibility or claims remain unknown, the program must first close the corresponding input before approving numerical limits and worst-case selection.

The evaluated boundary is Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. Testing can address the interface with separately supplied equipment, but it must not transform that equipment into an included kit component. Potential mechanical injury, loss of integrity, incompatibility and contamination questions are planning concerns, not asserted failures of this fictional product. The plan should cover appropriate final-device, processing and aging conditions, with a written rationale for the coverage claimed.

Dimensional and configuration verification

Planning record TST-01. Verify that the final manufactured configurations meet approved design requirements and support the claimed interfaces.

Profile basis	Final dimensions and tolerances are not supplied by the present structured profile.
Work to perform	1. Identify controlled drawings, relevant lumen and external dimensions, length and interface features for each marketed configuration. 2. Choose measurement methods, conditioning, sample rationale and representative configurations appropriate to those requirements. 3. Record results, deviations and disposition by device revision and relate any grouping to a justified coverage argument.
Evidence output	Dimensional verification protocol report and configuration coverage matrix.

Decision criteria	Measured characteristics meet approved criteria; unresolved tolerances or an unrepresented configuration block the associated coverage conclusion.
Responsible	Verification engineering
Prerequisites	SCP-02, QMS-02
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, ISO-11070-METADATA

Sheath and hub integrity

Planning record TST-02. Evaluate whether the device maintains integrity under relevant handling and procedural loads.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Identify relevant tensile, joint-retention or other integrity questions from the actual construction and risk analysis. 2. Define test fixtures, conditioning and loads that represent the intended use and justified worst cases; do not insert unsupported force limits. 3. Assess observed failures and damage, including potential separation or loss of function, with traceability to design requirements and controls.
Evidence output	Mechanical integrity protocols and evaluated reports.
Decision criteria	The tests address the actual construction and approved load criteria, and the review covers material deviations or failure mechanisms.
Responsible	Mechanical and verification engineering
Prerequisites	QMS-04, SCP-02
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, ISO-11070-METADATA

Flexibility kinking and functional patency

Planning record TST-03. Determine which bending or handling conditions can affect the sheath's intended function.

Profile basis	The profile identifies a sheath and hub, without controlled bending specifications or completed performance evidence.
Work to perform	1. Define relevant bend, handling and procedural conditions from design requirements and the intended clinical context. 2. Evaluate loss of patency, permanent deformation or loss of function using justified methods and acceptance criteria. 3. Relate any conditioning, final sterilization and aged-state evaluation to the risk and shelf-life strategy.

Evidence output	Functional bending and patency evidence with method rationale.
Decision criteria	The evidence covers clinically relevant conditions and final-device state; no unsupported fatigue life or kink-free claim is assigned.
Responsible	Design and verification engineering
Prerequisites	QMS-04, SCP-03, STD-02
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, ISO-11070-METADATA

Compatible equipment interfaces

Planning record TST-04. Show that the proposed compatibility claims are supported while preserving separately supplied equipment boundaries.

Profile basis	Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access.
Work to perform	1. Define the compatible device specifications and the contact/interface conditions that matter to function and safety. 2. Select representative or worst-case interfaces and evaluate passage, fit, handling and potential damage as appropriate. 3. Document coverage and limitations in the compatibility matrix and align the IFU with the evidence.
Evidence output	Compatibility verification and supported-interface matrix.
Decision criteria	Each claimed interface is covered by justified evidence and labeling; no broad universal compatibility is inferred from the device category.
Responsible	Design and verification engineering
Prerequisites	SCP-02, SCP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, FDA-SE

Particulate surface and finish assessment

Planning record TST-05. Address potential material shedding or surface characteristics relevant to the patient-contacting device.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. Materials: Not supplied
Work to perform	1. Identify plausible particulate and surface-related questions from construction, manufacturing, handling and compatibility use. 2. Define appropriate examination or quantitative methods, controls and acceptance criteria based on the final materials and risks. 3. Evaluate the finished processed device and investigate meaningful findings, linking any needed controls to manufacturing and labeling.
Evidence output	Particulate and surface assessment plan and evaluated evidence.
Decision criteria	The methods are appropriate to the actual risk and finished device; unsupported coating or non-pyrogenic performance is not asserted.
Responsible	Materials verification and risk functions
Prerequisites	SCP-05, QMS-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, FDA-BIOCOMP

Simulated clinical use

Planning record TST-06. Evaluate relevant integrated use conditions that isolated component tests may not adequately address.

Profile basis	Intended use: Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access.. Users: Trained healthcare professionals. Environment: Clinical setting; home use excluded..
Work to perform	1. Define representative task sequences and models that reflect the actual procedure, interfaces, users and limitations. 2. Identify observable failure or difficulty criteria and distinguish mechanical performance evaluation from separate human factors validation. 3. Record test configuration, sequence, observations, deviations and any required follow-up in risk or labeling controls.
Evidence output	Simulated-use protocol report and limitation assessment.
Decision criteria	The model and tasks are justified for the claimed use, and the conclusions do not extend to excluded populations, settings or anatomy.
Responsible	Verification engineering and clinical representative
Prerequisites	SCP-04, TST-04, QMS-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, FDA-HFE

Finished device biological evaluation

Planning record TST-07. Resolve the biological safety questions arising from actual patient exposures and final processing.

Profile basis	Contact: Not supplied. Duration: Not supplied. Materials: Not supplied.
Work to perform	1. Establish the contact category, duration and finished-device material/process inventory before choosing an evaluation approach. 2. Evaluate existing relevant data, chemical information and justified additional tests for the applicable questions using the FDA framework. 3. Retain the endpoint rationale, test-article relevance, limitations and specialist conclusions; reconcile changes in materials, processing and shelf life.
Evidence output	Biological evaluation plan and eventual evaluated report with endpoint evidence mapping.
Decision criteria	All relevant exposure questions have a justified conclusion; a material declaration or intake availability flag alone does not establish biological safety.
Responsible	Biological safety
Prerequisites	SCP-05, STD-03, QMS-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BIOCOMP

Sterilization packaging and evidence integration

The proposed method is Electron-beam irradiation. The validation strategy must follow that method, the actual finished-device family and the final packaging. Method selection and process validation are separate decisions. A supplied-sterile intake flag is a description of the intended product state; it does not establish microbiological assurance, process qualification or routine-release performance. Changes in material, geometry, supplier, loading or packaging can change the evidence needed.

Sterile-barrier protection and device shelf life should be evaluated together but not collapsed into one conclusion. Packaging process validation, package integrity, distribution exposure and aged functional performance answer distinct questions. Accelerated aging can support a planning approach when justified, while real-time evidence and the assumptions used must remain controlled. Acceptance limits, sample size and claimed expiry require an explicit technical rationale and actual evidence, not a generic date printed in a demonstration.

Method specific sterilization validation

Planning record TST-08. Demonstrate a defensible irradiation process for the final device and package without assuming a validated dose.

Profile basis	Electron-beam irradiation
Work to perform	1. Define the actual sterilization product family, bioburden strategy, dose-establishment approach and routine process controls. 2. Plan dose mapping and dosimetry for representative density, load and packaging arrangements; identify minimum and maximum product exposures for review. 3. Evaluate material, performance and package compatibility across the justified exposure range, including aging effects and changes requiring reassessment.
Evidence output	Electron-beam validation and routine-control plan with dose and compatibility evidence requirements.
Decision criteria	The dose and process are justified by controlled validation evidence for the final family and load; no numerical dose or validated performance is supplied by this report.
Responsible	Sterilization microbiology and quality assurance
Prerequisites	STD-04, STD-05, QMS-03, SCP-05
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STERILITY

Sterile barrier and packaging process

Planning record TST-09. Establish evidence that the final package can be reproducibly made and protect the sterile device through its intended life.

Profile basis	Not supplied
Work to perform	1. Define the final sterile-barrier materials, package configuration, sealing process and critical process variables. 2. Plan process validation and appropriate integrity, seal and visual assessments with justified configurations and acceptance criteria. 3. Link routine packaging acceptance and release controls to the validated process and evaluate changes that affect package performance.
Evidence output	Packaging process-validation and sterile-barrier evidence plan.
Decision criteria	The final package and process are covered by justified evidence; passing one integrity test does not establish all manufacturing or shelf-life requirements.
Responsible	Packaging engineering and quality assurance
Prerequisites	STD-06, SCP-02, QMS-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STERILITY, FDA-BENCH

Distribution and shelf life claim

Planning record TST-10. Support the proposed storage, shipping and expiry statements with relevant final-device and package evidence.

Profile basis	No controlled expiry or completed distribution/aging evidence is established in the current profile.
Work to perform	1. Define the expected distribution and storage conditions and justify the selected conditioning or simulation methods. 2. Select appropriate package and device evaluations after exposure and aging, accounting for final sterilization and worst-case configurations. 3. Document aging assumptions, real-time commitments where needed, failure investigation and the claim supported by the evaluated evidence.
Evidence output	Distribution and aging evidence plan with shelf-life claim rationale.
Decision criteria	The claimed life is supported for the actual device/package combination and conditions; a generic accelerated-aging calculation alone does not close the claim.
Responsible	Packaging materials and verification engineering
Prerequisites	TST-08, TST-09, SCP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STERILITY, FDA-BENCH

Sampling methods and laboratory qualification

Planning record TST-11. Make the test results interpretable and representative of the intended coverage.

Profile basis	The final test-article family and detailed material/dimensional specifications remain to be controlled.
Work to perform	1. For each evaluation, justify sample selection, size, conditioning, controls, repeatability and worst-case coverage based on the question being answered. 2. Verify laboratory competence, calibrated equipment, method suitability and the handling of invalid results or deviations. 3. Identify statistical or qualitative decision methods in the protocol before testing, with a rationale appropriate to the evidence category.
Evidence output	Test sampling method and laboratory qualification record.
Decision criteria	The program can explain why the evidence supports the claimed coverage; unsupported sample counts or laboratory claims are not inserted into the report.
Responsible	Verification engineering quality assurance and specialist laboratory
Prerequisites	SCP-02, STD-01, QMS-02

Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, FDA-BIOCOMP, FDA-STERILITY

Protocol approval and evidence review

Planning record TST-12. Control the criteria used to interpret evidence before execution and preserve an honest final conclusion.

Profile basis	This assessment plans work and has not reviewed completed underlying test records.
Work to perform	1. Approve the question, final device revision, method, sampling, acceptance criteria and deviation rules for each evaluation before execution. 2. Review actual reports for traceability, results, deviations, uncertainty and consistency with the protocol and intended claim. 3. Assign disposition, follow-up and limitations; retain a failure or unresolved result until an evidence-based closure decision is made.
Evidence output	Approved protocol register and evaluated evidence closure records.
Decision criteria	Every favorable conclusion is supported by the correct actual evidence and any limitations; planned testing is not presented as a completed successful result.
Responsible	Technical evidence owner and quality assurance
Prerequisites	QMS-02, QMS-04, STD-01, TST-11
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, FDA-BIOCOMP, FDA-STERILITY

Regulatory references

- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA-STANDARDS | Appropriate use of voluntary consensus standards | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final

guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.

- ISO-11070-METADATA | ISO 11070 public catalogue metadata | Source URL: <https://www.iso.org/standard/63315.html> | 2014 edition with 2018 amendment; publisher metadata checked. Exact current FDA recognition, extent and limitations remain to be verified. No standard clauses are reproduced.
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-HFE | FDA human factors engineering guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices> | Companion source identified by FDA; confirm device-specific applicability and current recommendations.

11 Software Regulatory Assessment

Applicability: not applicable | Confidence: high

Current regulatory position

Device software is not applicable to the evaluated configuration because every software-role field is explicitly absent.

Rationale

This result follows the structured software facts; it does not extend to a later software-enabled configuration. Any change to a software-role field requires reassessment.

Required evidence

- Controlled configuration record confirming the absence of device software functions.
[configuration]

Software boundary and reassessment

All structured software-role fields are absent in this bounded branch. The present device therefore does not receive an invented software lifecycle, firmware verification program or software safety classification. The exclusion still needs a controlled factual basis: device components, separately supplied equipment and manufacturing tools should not be conflated. Software used by a manufacturer can raise quality-process questions without becoming device software.

If a later configuration introduces device software, the current branch must no longer be treated as an adequate assessment. The intended function, architecture and applicable regulatory evidence must be reassessed through the appropriate route. This report's non-applicability conclusion is restricted to the evaluated configuration and does not certify an unreviewed future connected or software-enabled device.

Software absence and component inventory

Planning record SW-01. Support the non-applicability decision with a controlled factual boundary.

Profile basis	Embedded software firmware standalone software and mobile applications are explicitly absent in the evaluated profile.
Work to perform	1. Reconcile the device component register with all software-role declarations. 2. Distinguish separately supplied equipment and manufacturing/quality tools from software that is part of the marketed device. 3. Record the basis for absence and escalate any contradiction before retaining the non-applicability conclusion.
Evidence output	Software boundary and non-applicability record.
Decision criteria	The component facts support the exclusion; no software validation or lifecycle-compliance claim is made for this non-software configuration.
Responsible	Design engineering and regulatory affairs
Prerequisites	SCP-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-QMSR

Software change trigger

Planning record SW-02. Prevent a software-enabled revision from inheriting this bounded non-applicability decision.

Profile basis	The present non-powered branch does not assess a device software implementation.
Work to perform	1. Define triggers for adding embedded, standalone, firmware or mobile device functions. 2. Route the changed configuration to a suitable assessment and identify new evidence and pathway questions before release. 3. Update the controlled profile, risk and evidence register so the old exclusion is visibly superseded.
Evidence output	Software introduction reassessment rule in change control.
Decision criteria	A material software change receives a new assessment; existing absence flags cannot be reused as evidence for the changed product.
Responsible	Regulatory affairs and design engineering
Prerequisites	SW-01, CHG-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-QMSR

Regulatory references

- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>

12 Cybersecurity Regulatory Assessment

Applicability: not applicable | Confidence: high

Current regulatory position

Cybersecurity is not applicable to the evaluated configuration because the relevant software, connectivity, cloud, AI/ML and cybersecurity-presence fields are explicitly absent.

Rationale

Unknown presence is preserved as uncertainty. No inference about connectivity or a cyber-device determination is made from the device name or lack of a supplied cloud backend.

Required evidence

- Resolved architecture/configuration facts for connectivity, data paths and cyber-device applicability. [architecture]

Connectivity and cybersecurity boundary

The structured technology facts are connectivity: absent; cloud: absent; ai_ml: absent; cybersecurity_relevant: absent. Explicit absence supports the bounded exclusion; an unknown or present field leaves applicability unresolved. Lack of a cloud account or a device name alone does not establish cybersecurity non-applicability. The evidence needed is a controlled architecture and data-path description for the actual marketed system.

The current non-software sheath and hub should not receive a fabricated connected-device cybersecurity package. If connectivity, data storage, communication or software functions are proposed later, the system boundary and relevant obligations must be reassessed. Separately supplied equipment can create interface considerations, but its existence does not automatically make every cybersecurity characteristic part of this device.

Architecture and data path facts

Planning record CYB-01. Resolve the factual basis for cybersecurity applicability without converting unknown presence into absence.

Profile basis	connectivity: absent; cloud: absent; ai_ml: absent; cybersecurity_relevant: absent
Work to perform	1. Reconcile the actual hardware, software, connectivity, cloud and data-handling declarations against the controlled component and system description. 2. Identify any interface or function that is not fully described and retain it as an unresolved question. 3. Record a justified applicability decision or route the changed system to a separate suitable assessment.
Evidence output	Architecture and cybersecurity applicability record.
Decision criteria	Absence is supported by explicit facts and unknown states remain open; no automated cyber-device determination is inferred from a naming convention.
Responsible	Design engineering and regulatory affairs
Prerequisites	SCP-01, SW-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

Connected system change control

Planning record CYB-02. Ensure the present boundary decision does not hide new obligations in a later system configuration.

Profile basis	The current assessed branch has no device software; other technology applicability follows its own explicit presence fields.
Work to perform	1. Identify triggers involving device data, wired or wireless communication, remote functions, cloud processing or AI-related functions. 2. Reassess the marketed system and its evidence needs before implementation, including separately supplied interfaces where relevant. 3. Record the updated configuration, applicability decision and any specialist work needed before retaining a release claim.
Evidence output	Technology change and reassessment checklist.
Decision criteria	Changes receive an appropriate new evaluation; the present exclusion is not represented as permanent cybersecurity clearance.
Responsible	Regulatory affairs and system design
Prerequisites	CYB-01, CHG-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-QMSR

Regulatory references

- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>

13 Human Factors Usability Strategy

Applicability: applicable | Confidence: medium

Current regulatory position

Develop the use specification, task analysis and use-related risk assessment for the users, environments and device boundary supplied in this profile. Determine applicable FDA human-factors submission content from that assessment.

Rationale

Intended users: Trained healthcare professionals. Patient scope: Adults only; pediatric use excluded. Environment: Clinical setting; home use excluded. Training does not eliminate use-related risk; tasks for unprovided components or excluded users/environments are not added by the rules.

Required evidence

- Use specification, critical-task analysis and justified usability evaluation/validation plan for the final device. [human factors]

Recommended actions

- Approve the use-related risk assessment and determine the evidence needed for its actual critical tasks. [high]

Use related risk and human factors evidence

The supplied intended users are Trained healthcare professionals, the patient scope is Adults only; pediatric use excluded., and the environment is Clinical setting; home use excluded.. These facts define the use specification for the current planning case. Professional training does not remove the need to evaluate relevant use-related hazards, and the report must not add home, pediatric or excluded-use indications. Foreseeable misuse can be analyzed as risk without becoming a marketed claim.

The use-related analysis should address identification, compatibility selection, package inspection, aseptic presentation, relevant insertion/handling steps, recognizing loss of function and disposal as appropriate to the final design. Those are task questions to evaluate, not claims that the current IFU has already resolved them. The May 2026 FDA submission-content framework should be applied

with the human factors engineering guidance to decide the needed content and evidence. This report does not assign a content category or declare validation completed without supporting facts.

Use specification and task sequence

Planning record HFE-01. Define the tasks, users and context that the use-related evidence must represent.

Profile basis	Users: Trained healthcare professionals. Population: Adults only; pediatric use excluded.. Environment: Clinical setting; home use excluded..
Work to perform	1. Describe the actual procedure, user roles, prior training and environmental conditions using controlled inputs. 2. Map interactions from selection and package opening through relevant placement, handling, removal and disposal tasks. 3. Identify interface and instruction details still needed and keep excluded user populations or settings outside the claimed-use specification.
Evidence output	Use specification and task analysis tied to the final design.
Decision criteria	The task sequence covers the marketed use and actual interface; no absent component or excluded indication is introduced as a product fact.
Responsible	Human factors and clinical representative
Prerequisites	SCP-04, SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE, FDA-HFE-CONTENT

Use related hazard and critical task analysis

Planning record HFE-02. Identify tasks where failure can create relevant harm and connect them to controls and evidence.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Analyze use errors and foreseeable difficulties for the actual tasks, interfaces, labeling and environment. 2. Identify critical tasks and explain the associated hazard sequence and potential harm without inventing observed incidents. 3. Link controls to design, instructions, training assumptions and the evaluation needed to establish effectiveness.
Evidence output	Use-related risk analysis and critical-task control matrix.
Decision criteria	Critical tasks have a justified risk basis and evidence route; training or a warning is not assumed effective without evaluation.
Responsible	Human factors and risk management
Prerequisites	HFE-01, QMS-04

Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE

Formative evaluation and design improvement

Planning record HFE-03. Find meaningful use problems before the final evidence configuration is frozen.

Profile basis	No completed usability study or final IFU evaluation is established in the profile.
Work to perform	1. Choose evaluation methods and representative participants or specialist inputs appropriate to the development questions. 2. Capture use difficulties, comprehension gaps, interface problems and the resulting design or labeling changes. 3. Retain the rationale for decisions and re-evaluate material changes instead of treating a preliminary favorable observation as final validation.
Evidence output	Formative evaluation plan findings and design-response record.
Decision criteria	The evaluations address actual uncertainties and changes are traceable; preliminary evidence is not labeled as completed final validation.
Responsible	Human factors and design engineering
Prerequisites	HFE-02, LBL-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE

Validation need and representative conditions

Planning record HFE-04. Choose a defensible final use-related evidence approach based on the design and risk questions.

Profile basis	Users: Trained healthcare professionals. Use environment: Clinical setting; home use excluded..
Work to perform	1. Determine whether the applicable FDA framework calls for validation data or whether an alternative justified evidence rationale addresses the relevant questions. 2. Where a study is needed, define representative users, critical tasks, training conditions, environment and final interface/labeling. 3. Record study design, analysis and acceptance rationale before execution and justify any limitations or departures.
Evidence output	Human factors validation decision and protocol if applicable.
Decision criteria	The evidence approach follows the current framework and actual risks; no fixed participant count, validation success or exemption is invented.

Responsible	Human factors and regulatory affairs
Prerequisites	HFE-02, HFE-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE, FDA-HFE-CONTENT

Use evidence and submission content review

Planning record HFE-05. Provide a traceable human factors conclusion for the correct final configuration.

Profile basis	Human factors evidence has not been independently reviewed by the Strategy engine.
Work to perform	1. Review the actual evaluations or justified non-study rationale against the intended users, interface, critical tasks and current FDA content framework. 2. Explain observed use problems, residual risks, limitations, mitigation and any further evidence needed. 3. Prepare the appropriate submission content with exact record references and reconcile it with final labeling and risk conclusions.
Evidence output	Human factors evidence conclusion and submission-content record.
Decision criteria	The content and conclusion are supported by the actual final-design evidence; professional-user status alone does not close a critical-task question.
Responsible	Human factors and regulatory affairs
Prerequisites	HFE-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE-CONTENT, FDA-HFE

Instructions and use control traceability

Planning record HFE-06. Ensure the IFU and proposed training actually address the controls relied on by the risk analysis.

Profile basis	Actual labeling and training materials remain to be controlled and evaluated.
Work to perform	1. Map each instruction, warning or training assumption relied on as a control to its corresponding use-related hazard or critical task. 2. Evaluate comprehension and usability in the justified evidence approach and record limitations. 3. Reconcile final labeling revisions with the tested interface and assess material changes before release.
Evidence output	IFU and training control-to-evidence traceability table.

Decision criteria	Reliance on instructions or training has a supporting rationale and evaluation; copied generic warnings do not replace a verified control.
Responsible	Human factors and labeling function
Prerequisites	HFE-02, HFE-05, LBL-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE, FDA-SYMBOLS

Regulatory references

- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-ESTAR | FDA eSTAR program | Source URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- FDA-HFE | FDA human factors engineering guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices> | Companion source identified by FDA; confirm device-specific applicability and current recommendations.
- FDA-HFE-CONTENT | FDA human factors submission content guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions> | Final guidance May 2026; apply its risk-based content framework with the FDA human factors engineering guidance.
- FDA-SYMBOLS | FDA use of symbols in labeling | Source URL: <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling> | FDA permits symbols with adjacent explanation and conditionally permits stand-alone standardized symbols.

14 Clinical Evidence Strategy

Applicability: applicable | Confidence: medium

Current regulatory position

The need for new clinical data remains a device-specific decision. Assess whether predicate comparison and the complete nonclinical evidence address all relevant safety/effectiveness questions before deciding the clinical program.

Rationale

Neither Class II status nor an unselected predicate establishes that clinical evidence is unnecessary or that a clinical investigation is required. Unresolved technological differences and proposed claims must be assessed against the final device and evidence.

Required evidence

- Clinical-evidence rationale tied to claims, predicate differences and unresolved safety/effectiveness questions. [clinical rationale]

Recommended actions

- Document the clinical-evidence decision; seek FDA feedback when the remaining questions warrant it. [high]

Clinical evidence need and rationale

The need for new clinical data is a device-specific decision. It should follow the final indications, predicate comparison, technological differences and the ability of the complete nonclinical program to address relevant safety and effectiveness questions. Neither a Class II classification nor the existence of other introducers establishes that clinical evidence is unnecessary. Conversely, missing information in an intake does not automatically require a clinical investigation.

Document the clinical questions and the evidence considered for each one. A literature or public-record review can contribute to the rationale, but the relevance of the population, device, outcomes and limitations must be evaluated. If the remaining questions require a study, its regulatory, ethical and operational requirements must be assessed separately before any patient activity. This strategy authorizes no clinical work and invents no favorable clinical results.

Clinical safety and effectiveness questions

Planning record CLN-01. Identify clinical questions that the comparison and nonclinical evidence must address.

Profile basis	Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access. Claims: No detailed performance or labeling claim supplied
Work to perform	1. Review proposed indications and claims, intended patient scope and meaningful technological differences. 2. Identify questions that are not adequately answered by existing relevant evidence or the planned nonclinical approach. 3. Assign the evidence or FDA-feedback route for each unresolved question and record why that route is appropriate.
Evidence output	Clinical-question and evidence-rationale register.
Decision criteria	Each question follows the actual device and claims; the report makes no automatic clinical-study requirement or no-study conclusion.
Responsible	Clinical representative and regulatory affairs
Prerequisites	SCP-06, CMP-03, CMP-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

Existing clinical and literature evidence relevance

Planning record CLN-02. Evaluate whether available evidence meaningfully supports the specific device and proposed claims.

Profile basis	No complete clinical evidence file or literature appraisal has been verified by this profile-driven run.
Work to perform	1. Define an evidence search or assessment scope relevant to the actual clinical questions and device differences. 2. Review population, use, technology, outcomes, study design and limitations of each proposed evidence source. 3. Document the contribution and gaps without importing another device's outcomes as results for this device.
Evidence output	Existing-evidence relevance and limitations assessment.
Decision criteria	Each cited result is attributed to its actual source and evaluated for relevance; absence of a reported problem is not proof of safety.
Responsible	Clinical representative
Prerequisites	CLN-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

New clinical evidence decision

Planning record CLN-03. Decide whether the remaining questions need additional clinical data after the nonclinical and comparison assessment.

Profile basis	Predicate selection and complete nonclinical evidence review remain open.
Work to perform	1. Review the unresolved clinical questions against the final comparison and evaluated nonclinical evidence. 2. Document why a study is or is not needed, and identify focused FDA interaction when uncertainty materially affects the route. 3. If a study is justified, define its purpose and assess the required regulatory, ethics and operational permissions separately before initiation.
Evidence output	Clinical-evidence decision memorandum and conditional study planning brief.
Decision criteria	The decision is evidence-based and device-specific; no patient study, exemption or ethics approval is claimed or authorized by this strategy.
Responsible	Clinical and regulatory functions
Prerequisites	CLN-02, CMP-07, TST-12
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-510K

Clinical conclusion and claim alignment

Planning record CLN-04. Keep the final clinical rationale consistent with the marketed indications and evidence limitations.

Profile basis	No detailed performance or labeling claim supplied
Work to perform	1. Prepare a source-linked conclusion explaining how the evidence addresses each relevant clinical question. 2. Restrict claim wording to the population, use and performance supported by the final evaluated evidence. 3. Record residual uncertainties and any postmarket commitments or reassessment triggers justified by the actual evidence.
Evidence output	Clinical rationale and claim limitation record.
Decision criteria	The final conclusion does not overextend another device's evidence or hide unresolved safety/effectiveness questions.
Responsible	Clinical representative and regulatory affairs
Prerequisites	CLN-03, SCP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE

Regulatory references

- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-ESTAR | FDA eSTAR program | Source URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.

15 Labeling Requirements

Applicability: applicable | Confidence: medium

Current regulatory position

Prepare labeling that accurately reflects the final intended use, device boundary, patient/user/environment scope, supplied-sterile and single-use status, and proposed method (Electron-beam irradiation). Prescription-use status is supplied as present; confirm final prescription labeling and any applicable exemptions.

Rationale

Control compatibility, instructions, risk-based warnings, storage/expiry, identification and applicable UDI obligations. Do not describe an unprovided component, excluded user/environment, validated method, issued identifier or FDA clearance as an established fact. Artwork and symbol applicability require separate controlled review.

Required evidence

- Device/package/IFU labeling master reconciled with design inputs, risk controls, completed verification and applicable identifier requirements. [labeling]

Recommended actions

- Complete the device-specific labeling and symbol-applicability review after configuration and evidence decisions are frozen. [high]

Device package and instructions strategy

Labeling must follow the controlled intended purpose, device boundary, supported claims and actual evidence. The supplied device description is Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. The proposed sterilization method is Electron-beam irradiation. The labeling review must preserve excluded components, users, populations and settings and must not convert planned validation, compatibility or shelf life into established performance.

The visual symbol glossary in this report shows actual sourced implementations with adjacent explanations and references. It is a planning resource, not a released device label. A standardized symbol communicates a defined fact; it does not establish that the device is sterile, that its package is validated or that an identifier has been assigned. FDA permits symbols with adjacent explanatory text and permits stand-alone standardized symbols when the applicable conditions are met. Control the current edition, meaning, applicability, artwork source and final printed readability together.

UDI, catalogue and lot identifiers must be assigned through the actual controlled labeling and operational process. The report contains no fabricated issued UDI, product barcode, expiry date or manufacturer address. Shelf-life and storage statements need supporting package and device evidence. Prescription labeling needs a device-specific decision under the applicable conditions, even where the intake has selected prescription use.

IFU and indication master

Planning record LBL-01. Keep the instructions consistent with the marketed purpose and actual device configuration.

Profile basis	Fictional single-use catheter introducer sheath and proximal hub for temporary introduction of a separately supplied compatible catheter into an adult peripheral vein through clinician-established access. Users: Trained healthcare professionals
Work to perform	1. Create the IFU structure for intended use, relevant procedure, compatibility, preparation, handling and disposal using final design inputs. 2. Record contraindications, limitations, precautions and warnings based on the actual risk and evidence conclusions. 3. Reconcile the IFU with the intended-use master and evaluated interface before labeling freeze.
Evidence output	Controlled IFU content master and indication consistency checklist.

Decision criteria	Instructions address the actual device and supported use; no excluded anatomy, population, component or unsupported clinical claim is introduced.
Responsible	Labeling function clinical and regulatory affairs
Prerequisites	SCP-03, SCP-04, SCP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, 21-CFR-801.109

Device package identification

Planning record LBL-02. Identify the correct marketed device and responsible organization through controlled label content.

Profile basis	Synthetic Example Medical LLC Boundary: Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Determine applicable manufacturer/labeler identification, model/catalogue description and package information using actual roles and requirements. 2. Assign identifiers and production information through the controlled master and link them to the configuration and lot records. 3. Check readability, consistency and reconciliation with the submission and manufacturing record system.
Evidence output	Device and package label-content master with identifier responsibilities.
Decision criteria	Identity and traceability fields are correct and controlled; no address, lot, serial number or model assignment is fabricated by the report.
Responsible	Labeling and quality assurance
Prerequisites	SCP-02, REG-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-REG-LIST, 21-CFR-830.300

Sterile state and single use claims

Planning record LBL-03. Ensure the symbols and statements on the final label match evaluated final-device evidence.

Profile basis	Proposed process: Electron-beam irradiation. Supplied-sterile and single-use facts are explicitly present in this bounded branch.
Work to perform	1. Map the sterile-state, method and single-use statements to the approved process and device evidence. 2. Check that the method-specific symbol and explanation match the controlled method; retain an unresolved method as a labeling decision gap. 3. Define package-damage, handling and reuse-related instructions from the actual risk controls and evaluate their consistency with the final package and IFU.
Evidence output	Sterility and single-use label claim-to-evidence record.
Decision criteria	The final statements are supported and method matched; a symbol or intake flag is never treated as validation evidence.
Responsible	Sterilization labeling and regulatory affairs
Prerequisites	TST-08, TST-09, SCP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STERILITY, FDA-SYMBOLS, FDA-15223-5-148

Expiry storage and handling statements

Planning record LBL-04. Restrict shelf-life and environmental label claims to the device/package conditions actually supported.

Profile basis	The profile does not establish a controlled expiry or evaluated storage/distribution evidence.
Work to perform	1. Define proposed expiry, storage and handling statements from the actual product/package evidence program. 2. Reconcile printed statements with distribution, package integrity and aged functional evidence and with manufacturing release controls. 3. Record limitations and change triggers; avoid assigning generic expiry dates or temperature ranges from another device.
Evidence output	Expiry storage and handling claim substantiation record.
Decision criteria	Each numerical or qualitative statement has relevant final-device evidence and controlled implementation; unverified claims remain withheld.
Responsible	Packaging engineering and labeling
Prerequisites	TST-10, SCP-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-STERILITY, FDA-BENCH

Prescription labeling decision

Planning record LBL-05. Evaluate the applicable prescription-device conditions and the content required for safe professional use.

Profile basis	Prescription-use status is supplied as present; final labeling conditions and exemptions remain to be confirmed.
Work to perform	1. Confirm the actual prescription/OTC decision and applicable conditions with the controlled intended purpose and user scope. 2. Where prescription labeling applies, evaluate the appropriate Rx only statement and use information under the current regulation. 3. Reconcile the final wording and any justified exemptions with the IFU, package labeling and distribution arrangements.
Evidence output	Prescription-labeling applicability and final wording decision.
Decision criteria	The decision is device-specific and consistent with applicable conditions; professional users or Class II status alone do not establish every exemption.
Responsible	Regulatory affairs and labeling
Prerequisites	SCP-03, LBL-01
Evidence status	Planned work; supporting records have not been verified
Source references	21-CFR-801.109

UDI labeler and data responsibilities

Planning record LBL-06. Establish correct identification and data-submission responsibilities without inventing an issued identifier.

Profile basis	The actual labeler/model/identifier arrangement has not been established by this assessment.
Work to perform	1. Assess the applicable UDI labeling and device-data requirements, exceptions and labeler responsibilities using the actual marketed model and packaging. 2. Define issuing-agency, identifier, production-information and applicable GUDID processes through the authorized operational workflow. 3. Verify identifier consistency, data quality, change control and any direct-marking applicability separately before release.
Evidence output	UDI applicability data and label-control plan.
Decision criteria	Applicable identification and data obligations have accountable owners and actual records; the UDI symbol is not represented as an assigned UDI.
Responsible	Regulatory operations and labeling
Prerequisites	REG-01, SCP-02
Evidence status	Planned work; supporting records have not been verified
Source references	21-CFR-830.300

Actual symbols and explanations

Planning record LBL-07. Provide controlled actual symbol graphics with meanings and device-specific applicability decisions.

Profile basis	The licensed catalogue is a source of symbol implementations; the regulatory meaning and final application require their own review.
Work to perform	1. Select only relevant symbol entries and the appropriate method-specific sterilization graphic for the controlled profile. 2. Provide adjacent meaning text or the justified standardized-symbol/glossary approach with correct source designation and references. 3. Retain artwork provenance and license notices and evaluate the final printed size, contrast, orientation and comprehension as applicable.
Evidence output	Visual symbol glossary and artwork applicability register.
Decision criteria	The graphic, meaning, reference and intended claim agree; unauthorized regulatory marks and unsupported claims do not appear on a demonstration label.
Responsible	Labeling regulatory affairs and human factors
Prerequisites	SCP-06, STD-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SYMBOLS, FDA-SYMBOLS-FAQ, FDA-15223-5-148

Labeling release and reconciliation

Planning record LBL-08. Control the exact labeling revision used in the submission and commercial release.

Profile basis	No device label or IFU has been approved for commercial use by this sample.
Work to perform	1. Reconcile identity, indications, warnings, instructions, supported claims, symbols and identifiers across the package, IFU and submission. 2. Verify that the final evidence supports the actual printed content and that manufacturing/labeling operations use the approved master. 3. Retain review, release authority, obsolete-version controls and change triggers linked to the tested configuration.
Evidence output	Final labeling review and revision-release record.
Decision criteria	The released master is consistent with the final evidence and applicable obligations; unresolved claims or identifiers block their corresponding release statements.
Responsible	Quality assurance regulatory affairs and labeling

Prerequisites	LBL-02, LBL-03, LBL-04, LBL-05, LBL-06, LBL-07, HFE-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-SYMBOLS, 21-CFR-801.109

Visual labeling symbol glossary

The following actual symbol graphics are planning examples with adjacent explanations. Use the current applicable standard and final device evidence when releasing labeling. A method-specific graphic is shown only when the structured sterilization method is resolved.

Standard basis: ISO 15223-1 fourth edition 2021-07 including Amendment 1 2025, FDA recognition 5-148. The FDA record identifies December 17 2028 as the transition end for prior recognition 5-134.

Symbol	Meaning and reference	Application and decision
	Manufacturer ISO 15223-1 5.1.1 Identifies the manufacturer.	Place with the correct manufacturer identification where applicable; the report invents no address.
	Medical device ISO 15223-1 5.7.7 Identifies a medical device.	Use only for the controlled device and verified applicable labeling approach.
	Catalogue number ISO 15223-1 5.1.6 Identifies the catalogue or reference number.	Use the actual assigned identifier for the marketed model; no catalogue number is generated here.
	Batch code ISO 15223-1 5.1.5 Identifies the manufacturing batch or lot.	Link actual production information to release and traceability records; the report assigns no batch.
	Date of manufacture ISO 15223-1 5.1.3 Identifies the date of manufacture.	Use where appropriate with the actual controlled date; no date is assigned in this glossary.
	Do not reuse ISO 15223-1 5.4.2 Indicates that the device is intended for single use.	Match the controlled single-use statement and supporting risk/evidence decision.
	Consult instructions for use ISO 15223-1 5.4.3 Directs the user to the instructions for use.	Provide accessible controlled instructions for the actual intended users and device revision.

Symbol	Meaning and reference	Application and decision
	Caution ISO 15223-1 5.4.4 Directs attention to cautionary information.	Associate with relevant controlled warnings or precautions; the graphic alone does not communicate the full risk control.
	Do not use if package is damaged ISO 15223-1 5.2.8 Indicates not to use the device if its package is damaged and to consult the instructions.	Tie to the final sterile-barrier and package-inspection instructions and evidence.
	Unique device identifier ISO 15223-1 5.7.10 Identifies unique device identifier information.	Apply to actual assigned UDI information when applicable; the symbol does not assign or replace the identifier.
	Sterilized using irradiation ISO 15223-1 5.2.4 Indicates sterilization using irradiation.	Candidate method-matched symbol for the supplied electron-beam process; final use needs the approved sterile-state and process evidence.

Symbol artwork provenance

Artwork implementations from medical-device-symbols by Taig Mac Carthy. Source commit f83599e45613b269d4f85134bd1fd33ae2ef2a28. Converted from the pinned SVG files to black transparent PNGs with aspect ratio preserved. Each source and image hash is retained in the reviewed catalogue. The artwork is an implementation aid; its license does not determine device-specific regulatory applicability.

Artwork license source:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/LICENSE>

Manufacturer artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/manufacturer.svg>

Medical device artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/md.svg>

Catalogue number artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/catalogue-number.svg>

Batch code artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/batch-code.svg>

Date of manufacture artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/manufacture-date.svg>

Do not reuse artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/do-not-re-use.svg>

Consult instructions for use artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/consult-instructions-for-use.svg>

Caution artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/caution.svg>

Do not use if package is damaged artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/do-not-use-if-package-is-damaged.svg>

Unique device identifier artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/udi.svg>

Sterilized using irradiation artwork:

<https://github.com/t4dhg/medical-device-symbols/blob/f83599e45613b269d4f85134bd1fd33ae2ef2a28/src/icons/sterilized-using-irradiation.svg>

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Regulatory references

- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- 21-CFR-870.1340 | Catheter introducer classification | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870/subpart-B/section-870.1340>
- FDA-DYB | FDA product classification record DYB | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB> | Working code; verify the complete current record and final configuration before use.
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- 21-CFR-801.109 | Prescription device labeling | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801/subpart-D/section-801.109> | Current eCFR text retrieved October 13 2026; prescription status and exemption conditions need a final device-specific decision.
- FDA-REG-LIST | Role-specific registration and listing | Source URL: <https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>
- 21-CFR-830.300 | UDI data submission applicability | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-830/subpart-E/section-830.300> | Current eCFR text retrieved; assess labeler/model/UDI applicability and exceptions rather than inventing identifiers.
- FDA-SYMBOLS | FDA use of symbols in labeling | Source URL: <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling> | FDA permits symbols with adjacent explanation and conditionally permits stand-alone standardized symbols.
- FDA-15223-5-148 | FDA recognition 5-148 for ISO 15223-1 | Source URL: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=46534 | ISO 15223-1 fourth edition 2021-07 including Amendment 1 2025. FDA record checked October 13 2026; prior recognition 5-134 transition ends December 17 2028.
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.

- FDA-SYMBOLS-FAQ | FDA labeling symbols questions and answers | Source URL: <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling-frequently-asked-questions> | FDA explains adjacent text, standardized symbols, glossary content and glossary location.
- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>

16 Registration Licensing Requirements

Applicability: applicable | Confidence: medium

Current regulatory position

Determine role-specific establishment registration and device-listing obligations before commercial distribution. Confirm foreign-establishment, U.S.-agent and importer obligations only when the corresponding roles exist.

Rationale

Manufacturer country, establishment activities and importer arrangements are not supplied by this branch. A premarket planning position does not establish registration, listing, fee payment or authorization to distribute.

Required evidence

- Manufacturer/site/role register and documented applicability of registration, listing, agent and importer requirements. [establishment roles]

Recommended actions

- Confirm the actual establishment and distribution roles and assign completion owners. [high]

Establishment listing and distribution responsibilities

The supplied legal manufacturer name is Synthetic Example Medical LLC. Its actual locations, activities, contract arrangements and distribution roles are not established by this name. Registration and listing decisions must follow the activities performed by each establishment and the applicable current rules. They are separate from the premarket decision and do not establish FDA approval or a right to use approval language.

Identify actual manufacturing, sterilization, relabeling, importing and distribution arrangements before assigning obligations. Foreign-establishment and U.S.-agent questions apply only where those facts exist. The implementation plan should include current deadlines, fees, record ownership and changes in activity, but this report invents no country, registration number, listing, fee payment or representative appointment.

Establishment activity and role register

Planning record REG-01. Determine which actual entities perform the activities relevant to U.S. market entry.

Profile basis	Synthetic Example Medical LLC Manufacturing information: Not supplied
Work to perform	1. List the legal manufacturer and each actual site or contractor with its activities, location and responsible contact function. 2. Distinguish manufacture, sterilization, labeling, importing and other activities without assuming a role from a company name. 3. Map the applicable registration/listing and identification responsibilities to the actual arrangements and retain unresolved roles.
Evidence output	Establishment and commercial-role applicability matrix.
Decision criteria	Responsibilities follow actual activities and current sources; no unappointed agent or unsupported manufacturer country is asserted.
Responsible	Regulatory operations and quality assurance
Prerequisites	SCP-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-REG-LIST

Foreign establishment and importer decisions

Planning record REG-02. Evaluate foreign-establishment and distribution obligations only when the corresponding arrangements exist.

Profile basis	Actual site locations, importer roles and representative appointments remain unspecified.
Work to perform	1. Confirm whether any relevant establishment is foreign and identify the actual importer/distributor arrangements. 2. Evaluate U.S.-agent, importer and other role-specific duties using the current FDA requirements. 3. Retain actual appointments, agreements and obligation ownership before commercial release where required.
Evidence output	Foreign-establishment agent and importer applicability decisions.
Decision criteria	Every obligation has a factual applicability basis and responsible entity; the report does not assign an agent or create an appointment.
Responsible	Regulatory operations
Prerequisites	REG-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-REG-LIST

Registration and listing implementation

Planning record REG-03. Complete applicable registration/listing work through the actual authorized account and commercial workflow.

Profile basis	No actual registration, listing or fee-payment record is supplied for this fictional planning case.
Work to perform	1. Confirm current filing requirements, applicable fees, annual obligations and timing for each responsible establishment. 2. Prepare accurate device and activity information using the final marketed configuration and actual authorization where applicable. 3. Retain the filed records and accountable maintenance process; do not treat registration as premarket approval or clearance.
Evidence output	Registration listing and maintenance plan with actual completion records when performed.
Decision criteria	Applicable filings are accurate and current, and their limited regulatory meaning is preserved in external wording.
Responsible	Regulatory operations and authorized account owner
Prerequisites	REG-01, REG-02, PTH-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-REG-LIST, FDA-510K

Commercial distribution readiness

Planning record REG-04. Align regulatory, quality and operational obligations before the final device is distributed.

Profile basis	The candidate establishes no FDA decision, released device labeling or completed operational system.
Work to perform	1. Reconcile the actual authorization, applicable registrations/listings, labeling, UDI and establishment-role records. 2. Verify distribution traceability, complaint/reporting contacts and the ability to identify affected lots or configurations. 3. Retain an owned commercial-release decision and assess any later role, site or distribution change.
Evidence output	Commercial readiness and accountable release record.
Decision criteria	All applicable conditions are supported by actual records; unresolved authorization or operational obligations remain release gates.
Responsible	Quality assurance regulatory affairs and commercial operations
Prerequisites	REG-03, LBL-08, PMS-05
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-REG-LIST, FDA-MDR, FDA-RECALL

Regulatory references

- FDA-REG-LIST | Role-specific registration and listing | Source URL: <https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>
- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-MDR | Medical device reporting | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>
- FDA-RECALL | Corrections and removals | Source URL: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>

17 Postmarket Requirements

Applicability: applicable | Confidence: medium

Current regulatory position

Plan applicable complaint, adverse-event/MDR, corrections/removals, field-action and risk-feedback processes for the actual marketed device and responsible establishments.

Rationale

Use the final device's risks and operational roles to define escalation, reportability decisions and follow-up. Do not import event histories or component-specific failure claims from another device into this case.

Required evidence

- Controlled complaint/reportability and correction/removal workflows linked to the actual device risks and establishment responsibilities. [postmarket]

Recommended actions

- Verify operational readiness and record applicable legal reporting requirements before launch. [high]

Complaint reporting and field action readiness

Postmarket readiness should be established for the actual device and responsible establishments before distribution. The system needs a way to receive complaints and other information, identify the affected product and lot, investigate the issue, evaluate reportability and act on a risk signal. Potential issues such as loss of integrity, incompatibility, use difficulty, contamination or package damage are categories for a future operating system, not reported failures of this fictional device.

Manufacturer MDR duties include evaluating qualifying death, serious-injury and recurrent-malfunction information under the applicable rules. The retrieved 21 CFR 803.50 text includes a 30-calendar-day reporting period for its qualifying events. Other duties, including expedited or

supplemental reporting, require separate applicability review. Corrections/removals under 21 CFR 806.10 have their own reportability conditions, exemptions and 10-working-day clock. Investigation and corrective action should not silently postpone an applicable reporting deadline.

Complaint intake and investigation

Planning record PMS-01. Capture sufficient information to identify the device, evaluate risk and investigate a reported concern.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Define intake channels, minimum event/device/lot information, triage responsibility and escalation criteria. 2. Link returned-device evaluation, manufacturing records, relevant test methods and clinical context as appropriate to the actual issue. 3. Retain the investigation, conclusions, limitations and follow-up, with traceability to the affected configurations and risk controls.
Evidence output	Complaint intake investigation and device traceability workflow.
Decision criteria	Information is assessed and relevant records can be retrieved; a missing returned sample does not erase the need to evaluate available information.
Responsible	Quality assurance and technical investigation functions
Prerequisites	QMS-04, SCP-02
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-MDR

MDR reportability and reporting clocks

Planning record PMS-02. Make timely reportability decisions using actual event information and applicable manufacturer obligations.

Profile basis	No actual adverse event is asserted; the report defines an operating control to establish.
Work to perform	1. Assess information against the applicable death, serious-injury and malfunction reporting criteria using the current regulatory text. 2. Record awareness dates, rationale, responsible decision-maker and applicable standard, expedited or supplemental reporting obligations. 3. Assign backups and escalation controls so investigations do not cause a missed applicable reporting period.
Evidence output	MDR applicability decision tree and reporting-clock controls.
Decision criteria	Qualifying events under 21 CFR 803.50 are handled within its applicable 30-calendar-day period; other provisions and clocks are separately assessed and documented.
Responsible	Regulatory reporting and quality assurance

Prerequisites	PMS-01, REG-01
Evidence status	Planned work; supporting records have not been verified
Source references	21-CFR-803.50, FDA-MDR

Corrections removals and affected product scope

Planning record PMS-03. Determine the regulatory and operational response when an issue requires action on distributed devices.

Profile basis	No field correction, removal or recall is claimed for this fictional planning case.
Work to perform	1. Assess the reason for the action, health risk, applicable exceptions and reportability under current requirements. 2. Identify affected models/lots, quantities, consignees and communications from actual distribution and manufacturing records. 3. Control decision authority, applicable reporting clocks, action execution and effectiveness checks, retaining rationale for non-reportable actions.
Evidence output	Correction/removal and field-action decision workflow.
Decision criteria	Reportable actions under 21 CFR 806.10 follow its applicable 10-working-day clock; exceptions and scope are justified with actual records.
Responsible	Quality assurance regulatory affairs and commercial operations
Prerequisites	PMS-01, REG-01
Evidence status	Planned work; supporting records have not been verified
Source references	21-CFR-806.10, FDA-RECALL

Signal trending and risk feedback

Planning record PMS-04. Use development and field evidence to reassess risks and controls instead of relying on an unchanging initial report.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Define meaningful complaint and failure categories for the actual device and the denominators needed to interpret trends where applicable. 2. Evaluate signals with investigation findings, use-related evidence, process data and current risk assumptions. 3. Assign resulting design, labeling, supplier, process or reporting actions and review their effectiveness.
Evidence output	Device-specific trend review and risk-feedback register.
Decision criteria	Signals are interpreted with relevant context and actual data; no incident rate or favorable field history is invented.

Responsible	Quality assurance risk management and regulatory affairs
Prerequisites	PMS-01, QMS-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-MDR, FDA-RECALL

Operational readiness and effectiveness

Planning record PMS-05. Verify that complaint, reporting and field-action controls can operate before commercial release.

Profile basis	No implemented commercial operating system is certified by this sample Strategy assessment.
Work to perform	1. Confirm roles, trained backups, record access, communication routes and decision authority for applicable obligations. 2. Exercise the workflow with fictional scenarios in an authorized non-production setting and document identified gaps. 3. Close material process gaps and define routine effectiveness review, preserving applicable reporting and privacy controls.
Evidence output	Postmarket operational readiness and effectiveness record.
Decision criteria	The responsible organization can identify, investigate, escalate and act on relevant information; a written procedure alone is not assumed effective.
Responsible	Quality assurance and regulatory operations
Prerequisites	PMS-02, PMS-03, PMS-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-MDR, FDA-RECALL

Regulatory references

- FDA-MDR | Medical device reporting | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>
- FDA-RECALL | Corrections and removals | Source URL: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>
- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
- 21-CFR-803.50 | Manufacturer medical device reporting | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803/subpart-E/section-803.50> | Current text retrieved. Includes qualifying death/serious injury and recurrent-malfunction reporting within 30 calendar days; assess other applicable reporting provisions separately.

- 21-CFR-806.10 | Reports of corrections and removals | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-806/subpart-B/section-806.10> | Current text retrieved. Assess reportability, exemptions and the applicable 10-working-day report clock.

18 Regulatory Change Management

Applicability: applicable | Confidence: medium

Current regulatory position

Assess changes to intended use, patient/user/environment scope, actual components/materials/interfaces, claims, proposed sterilization method, packaging, shelf life and manufacturing/supplier arrangements before implementation.

Rationale

A change can affect classification/pathway, substantial equivalence, verification coverage, biological evaluation, sterility, labeling and the need for a new submission. This assessment retains the supplied boundary instead of assuming an old kit architecture.

Required evidence

- Versioned baseline and documented regulatory/evidence impact assessment for each proposed design or process change. [change control]

Recommended actions

- Maintain a controlled profile and reassess affected modules for each material change. [high]

Change impact and evidence continuity

Changes should be evaluated against a controlled baseline before implementation. For the sheath and hub, relevant changes include intended use, patient/user/environment scope, dimensions, materials, interfaces, claims, processing, sterile-barrier configuration, shelf life, sites and suppliers. Adding a component can change scope and classification rather than simply requiring another drawing. A new sterile-device method can change biological, mechanical, package and labeling evidence together.

The change record should identify affected requirements, risks, comparison arguments and evidence, then define the work needed to preserve or revise each conclusion. It should separately address any new-submission decision under applicable FDA rules and guidance. This report does not automatically decide that a modification is exempt from submission or that every change requires a new 510(k). The final decision depends on the actual change and the existing authorized device baseline.

Baseline and change request record

Planning record CHG-01. Make a proposed change and its affected configuration reproducible before assessing its consequences.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating.
Work to perform	1. Retain the approved profile, intended-purpose master, configuration, claims and applicable evidence revisions as the baseline. 2. Record the proposed change, reason, affected variants, sites or suppliers and the proposed implementation stage. 3. Assign the review functions and preserve the assessment history rather than replacing the baseline description without traceability.
Evidence output	Controlled baseline and change-request register.
Decision criteria	Reviewers can identify exactly what changed and which conclusions may be affected; the current report is not silently reused for a different device.
Responsible	Design engineering and quality assurance
Prerequisites	SCP-01, SCP-02, SCP-03
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-SE

Regulatory and claim impact

Planning record CHG-02. Assess classification, pathway, intended-use and comparison consequences of a proposed modification.

Profile basis	No existing clearance or modification history is established for this fictional case.
Work to perform	1. Compare the changed intended purpose, configuration and claims with the actual authorized baseline where one exists. 2. Evaluate whether the change affects classification, safety/effectiveness questions, labeling or a new-submission decision using applicable current sources. 3. Record the rationale, required evidence and any regulatory interaction before authorizing implementation.
Evidence output	Regulatory change and submission-impact assessment.
Decision criteria	The decision follows actual baseline and change facts; no automatic exemption or prior-clearance assertion is made.
Responsible	Regulatory affairs
Prerequisites	CHG-01, CLS-02, CMP-07
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-510K, FDA-SE

Material and process evidence impact

Planning record CHG-03. Evaluate whether the changed finished device remains covered by the existing or planned evidence.

Profile basis	Materials: Not supplied. Proposed process: Electron-beam irradiation.
Work to perform	1. Identify changes in material grade, additives, manufacturing residues, sterilization, packaging, suppliers or sites. 2. Assess the effects on biological exposure, process/product-family coverage, functional performance and sterile-barrier evidence. 3. Define required bridging, requalification or new evidence and retain the specialist rationale and limitations.
Evidence output	Material process and validation impact matrix.
Decision criteria	Evidence continuity is justified for the actual change; similarity of a nominal material or supplier certificate does not establish complete coverage.
Responsible	Materials biological safety sterilization and packaging functions
Prerequisites	CHG-01, SCP-05, STD-04, STD-06
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BIOCOMP, FDA-STERILITY, FDA-BENCH

Use labeling and technology impact

Planning record CHG-04. Prevent changed instructions, users or system functions from inheriting outdated applicability conclusions.

Profile basis	Users: Trained healthcare professionals. Environment: Clinical setting; home use excluded..
Work to perform	1. Review effects on critical tasks, interface, training, compatibility statements and supported claims. 2. Assess introduced power, software, connectivity or other functions through an appropriate new profile and assessment route. 3. Update labeling, risk and evidence controls and evaluate whether previous use-related evidence remains representative.
Evidence output	Use labeling and technology change-impact record.
Decision criteria	Changed functions and users receive appropriate reassessment; non-applicability decisions remain restricted to the evaluated configuration.
Responsible	Human factors design and regulatory affairs
Prerequisites	CHG-01, HFE-02, LBL-01, SW-01, CYB-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-HFE, FDA-SE, FDA-QMSR

Change authorization and implementation

Planning record CHG-05. Release a modification only after its affected evidence and operational obligations are resolved.

Profile basis	This sample implements no actual product or production-system change.
Work to perform	1. Consolidate technical, regulatory, supplier, labeling and operational impact conclusions with remaining open items. 2. Obtain authorization appropriate to the change and execute controlled updates to specifications, processes, training and records. 3. Verify implementation and effectiveness and retain the new baseline with its applicable evidence and release decision.
Evidence output	Change authorization implementation and effectiveness record.
Decision criteria	The implemented device matches the reviewed change and all consequential open items are addressed before their associated release claims.
Responsible	Quality assurance with accountable technical and regulatory owners
Prerequisites	CHG-02, CHG-03, CHG-04
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-QMSR, FDA-SE

Regulatory references

- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-ESTAR | FDA eSTAR program | Source URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>

- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- FDA-HFE | FDA human factors engineering guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices> | Companion source identified by FDA; confirm device-specific applicability and current recommendations.

19 Open Issues Decisions Required

Applicability: applicable | Confidence: medium

Current regulatory position

The assessment is a partial planning result; configuration, predicate, evidence and release decisions remain open.

Rationale

Structured profile facts and evidence-presence indicators do not establish a frozen design, completed tests, compliance, substantial equivalence or regulatory sign-off.

Open questions

- Freeze the final device boundary, materials, dimensions, compatibility, claims and marketed configuration.
- Confirm current product-code fit, applicable exemption limitations and the final premarket pathway.
- Select and justify a legally marketed predicate; no equivalence conclusion is established.
- Approve the evidence plan for the supplied sterilization method (Electron-beam irradiation); establish validation and routine-control evidence without inventing results.
- Resolve patient-contact category/duration, biological evaluation, packaging and proposed shelf life.
- Confirm the actual manufacturing, sterilization, establishment and distribution roles.
- Complete current-source review and regulatory approval before any public sample release.

Required evidence

- Owned decision register with source/evidence links and approval status. [decisions]

Recommended actions

- Close the applicable decision gates and approve the exact final report before external use. [high]

Open decisions and controlled closure

The current planning result has a working classification and pathway, but it does not establish a frozen marketed design, selected predicate, completed evidence, released labeling or authorization

to distribute. The decision register should preserve those distinctions. A comprehensive Strategy can explain the work and its acceptance basis while still concluding that evidence or regulatory questions remain open.

Close decisions using actual sources and evaluated evidence. Record an owner, prerequisite, decision criteria, disposition and resulting change to the strategy. High-impact issues should remain visible in the executive view and the evidence traceability table. The exact public demonstration input and output also need their own release decision, distinct from the automated service's optional professional-review offering.

Owned decision and issue register

Planning record DEC-01. Make missing facts and consequential decisions visible throughout development and submission preparation.

Profile basis	The assessment is partial planning and does not verify underlying technical-file evidence.
Work to perform	1. Record open configuration, source, predicate, biological, sterilization, packaging, labeling and operational decisions with accountable functions. 2. Define prerequisites, information needed, acceptance basis and consequence of leaving each decision open. 3. Maintain status and reviewed disposition without erasing the history of changed conclusions.
Evidence output	Owned issue and decision register with evidence links.
Decision criteria	Each consequential open question has a closure route and reviewer authority; the report does not substitute planned work for a completed decision.
Responsible	Program lead regulatory affairs and quality assurance
Prerequisites	SCP-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-QMSR

Evidence and claim closure review

Planning record DEC-02. Determine which claims and submission conclusions the actual evaluated evidence can support.

Profile basis	No detailed performance or labeling claim supplied
Work to perform	1. Review requirement, risk, comparison and evidence traceability together for the final configuration. 2. Identify unresolved limitations, failed evaluations or missing source/evidence facts that affect a proposed conclusion. 3. Record supported, withheld or conditional claims and the additional work or decision needed for each limitation.

Evidence output	Evidence closure and supported-claim decision record.
Decision criteria	A favorable conclusion follows relevant actual evidence and disclosed limitations; gaps cannot be closed through formatting or page count.
Responsible	Regulatory affairs quality assurance and technical evidence owners
Prerequisites	QMS-05, CMP-07, CLN-04, HFE-05
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-BENCH, FDA-BIOCOMP, FDA-STERILITY

Public sample and release scope

Planning record DEC-03. Approve the exact fictional demonstration and report separately from any production deployment or device market authorization.

Profile basis	This is an independently authored fictional sample from a candidate reporting workflow, rather than live deployed product output.
Work to perform	1. Review the frozen fictional input, substantive report depth, source currency, artwork provenance and limitations of the actual generated output. 2. Keep prior customer-derived or provenance-uncleared examples on their existing publication holds and retain only the approved independent material. 3. Record the owner's separate publication decision after applicable technical and source checks; preserve deployment and paid-run gates as distinct actions.
Evidence output	Exact demonstration-input and report release decision with artifact identities.
Decision criteria	The approved public artifact matches the reviewed output and does not imply production equivalence, device clearance or a mandatory consultant review for the automated service.
Responsible	Owner and accountable report reviewers
Prerequisites	DEC-01, DEC-02, LBL-07
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SYMBOLS, FDA-SE

Regulatory references

- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.

- FDA-QMSR | Quality Management System Regulation | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- FDA-SYMBOLS | FDA use of symbols in labeling | Source URL: <https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling> | FDA permits symbols with adjacent explanation and conditionally permits stand-alone standardized symbols.

20 Regulatory Strategy Executive Summary

Applicability: applicable | Confidence: medium

Current regulatory position

For CI-01 Independent Method Regression Sheath, retain the supplied device boundary and use Class II / 21 CFR 870.1340 / provisional DYB with Traditional 510(k) as the working U.S. planning position. Proposed sterilization method: Electron-beam irradiation. The evidence plan covers the actual dimensional/mechanical, use-related, biological, sterility and packaging/shelf-life questions. No additional kit component, coating, predicate, test result, validated process, exemption or FDA clearance is established. All software roles are explicitly absent; other technology applicability follows its own supplied presence fields. The output remains a partial profile-driven candidate assessment requiring final configuration, current-source, evidence and release review.

Rationale

The summary is assembled from the same profile and module decisions; it does not substitute for missing evidence or regulatory approval.

Recommended actions

- Review the working pathway and evidence plan against the frozen profile, then approve or correct the exact output. [high]

Program priorities and decision roadmap

The working U.S. strategy is to control the sheath/hub design and intended purpose, confirm the product-code and pathway decisions, select and justify a legally marketed comparator, then execute

an evidence program matched to the actual finished-device risks. In this case the supplied sterile single-use and patient-contact facts require a real evidence strategy for biological evaluation, the selected sterilization process, package protection, use and functional performance. Software and cybersecurity exclusions remain restricted to their explicit factual bases.

The first priorities are the configuration/material/contact inputs and current regulatory-source decisions, followed by protocol and comparison planning. The later decisions concern evaluated evidence, claim and labeling release, submission authorization and operational readiness. The plan should be scheduled from actual prerequisites and resources; it provides no guaranteed clearance date, invented test budget or implied authorization to provision infrastructure. The following milestones separate decision readiness from completed evidence and external release.

Baseline and strategy decision milestone

Planning record EXE-01. Establish the facts and regulatory rationale needed before committing the main evidence program.

Profile basis	Non-powered catheter introducer sheath and proximal hub only. No supplied catheter, needle, wire, dilator, valve, side port, or coating. Proposed method: Electron-beam irradiation
Work to perform	1. Close the controlled boundary, purpose, configurations, materials and patient-contact information needed for planning. 2. Confirm the current classification/pathway and complete the justified comparator-selection strategy. 3. Record the evidence questions, applicable sources, owners and remaining decisions in the controlled program plan.
Evidence output	Baseline and regulatory strategy milestone decision.
Decision criteria	The proposed work follows controlled inputs and justified regulatory questions; unresolved material facts are visible in the resource and schedule plan.
Responsible	Program lead and regulatory affairs
Prerequisites	SCP-05, CLS-02, PTH-01, CMP-07, DEC-01
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-SE, FDA-510K

Evidence execution and reconciliation milestone

Planning record EXE-02. Make the resulting evidence useful for a coherent final regulatory argument.

Profile basis	No completed verification, validation or clinical evidence conclusion is established by this planning assessment.
Work to perform	1. Authorize protocols with justified methods, sampling, conditions and acceptance criteria for the final configuration. 2. Execute through the actual authorized technical workflow and evaluate results, deviations, risk controls and claim limitations. 3. Reconcile final comparison, biological, sterile-device, packaging, use-related and labeling conclusions before submission freeze.
Evidence output	Evaluated evidence and final-claim milestone review.
Decision criteria	The evidence addresses the intended questions and final device; outstanding failures, limitations or missing facts remain explicit.
Responsible	Technical program lead quality assurance and regulatory affairs
Prerequisites	TST-12, QMS-05, DEC-02, LBL-08
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-BENCH, FDA-BIOCOMP, FDA-STERILITY, FDA-HFE-CONTENT

Submission and operational release milestones

Planning record EXE-03. Control the transition from a complete evidence package to authorized submission and eventual distribution.

Profile basis	The present report claims no FDA decision, filed submission or released commercial device.
Work to perform	1. Approve the exact submission package and its controlled attachments through the responsible applicant workflow. 2. Track the actual FDA process and reconcile any responses or changes without treating administrative acceptance as clearance. 3. Complete applicable operational and commercial-release obligations using actual records, then maintain postmarket and change controls.
Evidence output	Submission authorization FDA decision and commercial readiness milestone records.
Decision criteria	Each milestone has its own evidence and responsible decision; a complete Strategy report is not itself authorization to market or deploy a service.
Responsible	Regulatory affairs quality assurance and authorized commercial owners
Prerequisites	SUB-06, REG-04, PMS-05
Evidence status	Planned work; supporting records have not been verified
Source references	FDA-510K, FDA-REG-LIST, FDA-MDR, FDA-RECALL

Regulatory references

- 21-CFR-870.1340 | Catheter introducer classification | Source URL: <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870/subpart-B/section-870.1340>
- FDA-DYB | FDA product classification record DYB | Source URL: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB> | Working code; verify the complete current record and final configuration before use.
- FDA-510K | Premarket notification 510(k) | Source URL: <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- FDA-ESTAR | FDA eSTAR program | Source URL: <https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- FDA-STERILITY | FDA sterility information guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- FDA-SE | FDA substantial equivalence guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k> | Final guidance July 2014; landing page checked October 13 2026.
- FDA-BENCH | FDA nonclinical bench performance report guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket> | Final guidance December 2019; bench-report scope excludes separate biological, sterility, human factors and software evaluations.
- FDA-BIOCOMP | FDA biological evaluation guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA-HFE-CONTENT | FDA human factors submission content guidance | Source URL: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions> | Final guidance May 2026; apply its risk-based content framework with the FDA human factors engineering guidance.
- FDA-REG-LIST | Role-specific registration and listing | Source URL: <https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>
- FDA-MDR | Medical device reporting | Source URL: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>
- FDA-RECALL | Corrections and removals | Source URL: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>

Planning evidence and responsibility index

This index links each planning record to its evidence output, prerequisites and responsible function. The detailed record defines its work and acceptance basis. Evidence status in these records concerns verification by this assessment, and does not convert an intake availability declaration into a completed evidence review.

Record	Evidence output	Prerequisites	Responsible
SCP-01	Controlled device description and component applicability register.	None	Design engineering and regulatory affairs
SCP-02	Revision-controlled configuration and dimensional matrix.	SCP-01	Design engineering
SCP-03	Intended-use and indication master with approved exclusions.	SCP-01	Regulatory affairs and clinical representative
SCP-04	Use specification linked to the intended-purpose master.	SCP-03	Clinical and human factors functions
SCP-05	Contact and finished-device material inventory.	SCP-01, SCP-03	Materials engineering and biological safety
SCP-06	Claim-to-evidence register with proposed supported and withheld wording.	SCP-03	Regulatory affairs and design engineering
CLS-01	Classification rationale tied to the final profile revision.	SCP-01, SCP-03	Regulatory affairs
CLS-02	Current FDA product-code decision and evidence of the record checked.	CLS-01	Regulatory affairs
CLS-03	Alternative-scope screening log with conclusions and open questions.	SCP-01	Regulatory affairs and design engineering
PTH-01	Premarket pathway decision with sources assumptions and alternatives.	CLS-02, SCP-03	Regulatory affairs
PTH-02	FDA interaction decision and a question package if justified.	CMP-07, TST-12	Regulatory affairs and relevant technical function
PTH-03	eSTAR field and attachment plan with a controlled template decision.	PTH-01, SUB-01	Submission coordinator and regulatory affairs
PTH-04	Premarket and commercial release gate register.	DEC-01, REG-03, LBL-08	Regulatory affairs and quality assurance
CMP-01	Predicate search protocol and screening log.	SCP-03, CLS-02	Regulatory affairs
CMP-02	Candidate legal-status and source record.	CMP-01	Regulatory affairs

Record	Evidence output	Prerequisites	Responsible
CMP-03	Intended-use comparison with source-linked differences.	CMP-02, SCP-04	Regulatory affairs and clinical representative
CMP-04	Technological-characteristics comparison matrix.	SCP-02, SCP-05, CMP-02	Design engineering and regulatory affairs
CMP-05	Processing and biological difference assessment.	SCP-05, CMP-04	Biological safety and sterilization functions
CMP-06	Difference-to-evidence traceability matrix.	CMP-04, TST-01, TST-12	Design engineering and regulatory affairs
CMP-07	Predicate-selection memorandum with the comparison and evidence rationale.	CMP-03, CMP-05, CMP-06	Regulatory affairs
REQ-01	Source-linked U.S. requirements and applicability register.	CLS-02, SCP-01	Regulatory affairs and quality assurance
REQ-02	Claim and requirement evidence register with closure status.	SCP-06, CMP-06	Regulatory affairs and design engineering
REQ-03	Role-based obligations calendar and operating responsibility matrix.	REG-01, LBL-06, PMS-02	Quality assurance and regulatory operations
REQ-04	Requirement closure and exception log.	REQ-01, DEC-01	Quality assurance and regulatory affairs
GDN-01	Guidance applicability and currency register.	REQ-01	Regulatory affairs
GDN-02	Bench documentation plan and discipline-specific evidence index.	TST-12	Verification engineering and regulatory affairs
GDN-03	Human factors content-category rationale and supporting record list.	HFE-02, HFE-05	Human factors and regulatory affairs
GDN-04	Specialized-guidance applicability and decision record.	SCP-05, STD-03, STD-04	Biological safety sterilization and regulatory affairs
STD-01	Controlled standards and recognition matrix with source dates.	REQ-01	Regulatory affairs and verification engineering
STD-02	Introducer-standard applicability and protocol mapping.	SCP-01, SCP-02, STD-01	Verification engineering and regulatory affairs
STD-03	Biological evaluation standards and evidence rationale.	SCP-05, STD-01	Biological safety
STD-04	Sterilization standards applicability and validation evidence matrix.	STD-01, SCP-05	Sterilization function and regulatory affairs

Record	Evidence output	Prerequisites	Responsible
STD-05	Microbiological methods and suitability evidence plan.	STD-04	Microbiology and sterilization functions
STD-06	Packaging-standard and shelf-life method matrix.	STD-01, SCP-06	Packaging engineering and quality assurance
STD-07	Risk and quality framework applicability mapping.	STD-01, QMS-01	Quality assurance and risk management
STD-08	Controlled symbol glossary and artwork-source register.	LBL-07, STD-01	Regulatory affairs and labeling function
QMS-01	Design and development plan with stage gates and record index.	SCP-01, SCP-03	Design lead and quality assurance
QMS-02	Design input and output traceability matrix.	SCP-02, SCP-05, SCP-06	Design engineering
QMS-03	Critical-supplier matrix and outsourced-process control plan.	QMS-02, STD-04, STD-06	Supplier quality and manufacturing
QMS-04	Device-specific risk-management plan and analysis with control verification links.	SCP-01, SCP-04, SCP-05	Risk management with design clinical and quality functions
QMS-05	Requirement risk and evidence traceability matrix.	QMS-02, QMS-04, TST-12	Verification engineering and quality assurance
QMS-06	Design-transfer and critical-process validation plan.	QMS-03, TST-08, TST-09	Manufacturing packaging sterilization and quality assurance
QMS-07	Controlled document record and competence matrix.	QMS-01, QMS-06	Quality assurance
QMS-08	Nonconformity and CAPA workflow linked to device risk and change control.	QMS-04, PMS-01	Quality assurance with technical and regulatory owners
SUB-01	Submission section and attachment register.	SCP-01, PTH-01	Submission coordinator and regulatory affairs
SUB-02	Device description and predicate comparison attachment set.	SCP-02, CMP-07	Regulatory affairs and design engineering
SUB-03	Evidence summaries with a complete-report traceability index.	TST-12, QMS-05	Technical evidence owners and submission coordinator
SUB-04	Reviewed standards declarations and limitations record.	STD-01, QMS-05	Regulatory affairs and quality assurance

Record	Evidence output	Prerequisites	Responsible
SUB-05	Administrative and labeling reconciliation checklist with record references.	LBL-08, REG-01, SCP-03	Regulatory operations and labeling function
SUB-06	Submission freeze record and regulatory response change log.	SUB-02, SUB-03, SUB-04, SUB-05	Submission coordinator and regulatory affairs
TST-01	Dimensional verification protocol report and configuration coverage matrix.	SCP-02, QMS-02	Verification engineering
TST-02	Mechanical integrity protocols and evaluated reports.	QMS-04, SCP-02	Mechanical and verification engineering
TST-03	Functional bending and patency evidence with method rationale.	QMS-04, SCP-03, STD-02	Design and verification engineering
TST-04	Compatibility verification and supported-interface matrix.	SCP-02, SCP-06	Design and verification engineering
TST-05	Particulate and surface assessment plan and evaluated evidence.	SCP-05, QMS-04	Materials verification and risk functions
TST-06	Simulated-use protocol report and limitation assessment.	SCP-04, TST-04, QMS-04	Verification engineering and clinical representative
TST-07	Biological evaluation plan and eventual evaluated report with endpoint evidence mapping.	SCP-05, STD-03, QMS-04	Biological safety
TST-08	Electron-beam validation and routine-control plan with dose and compatibility evidence requirements.	STD-04, STD-05, QMS-03, SCP-05	Sterilization microbiology and quality assurance
TST-09	Packaging process-validation and sterile-barrier evidence plan.	STD-06, SCP-02, QMS-03	Packaging engineering and quality assurance
TST-10	Distribution and aging evidence plan with shelf-life claim rationale.	TST-08, TST-09, SCP-06	Packaging materials and verification engineering
TST-11	Test sampling method and laboratory qualification record.	SCP-02, STD-01, QMS-02	Verification engineering quality assurance and specialist laboratory

Record	Evidence output	Prerequisites	Responsible
TST-12	Approved protocol register and evaluated evidence closure records.	QMS-02, QMS-04, STD-01, TST-11	Technical evidence owner and quality assurance
SW-01	Software boundary and non-applicability record.	SCP-01	Design engineering and regulatory affairs
SW-02	Software introduction reassessment rule in change control.	SW-01, CHG-01	Regulatory affairs and design engineering
CYB-01	Architecture and cybersecurity applicability record.	SCP-01, SW-01	Design engineering and regulatory affairs
CYB-02	Technology change and reassessment checklist.	CYB-01, CHG-01	Regulatory affairs and system design
HFE-01	Use specification and task analysis tied to the final design.	SCP-04, SCP-03	Human factors and clinical representative
HFE-02	Use-related risk analysis and critical-task control matrix.	HFE-01, QMS-04	Human factors and risk management
HFE-03	Formative evaluation plan findings and design-response record.	HFE-02, LBL-01	Human factors and design engineering
HFE-04	Human factors validation decision and protocol if applicable.	HFE-02, HFE-03	Human factors and regulatory affairs
HFE-05	Human factors evidence conclusion and submission-content record.	HFE-04	Human factors and regulatory affairs
HFE-06	IFU and training control-to-evidence traceability table.	HFE-02, HFE-05, LBL-01	Human factors and labeling function
CLN-01	Clinical-question and evidence-rationale register.	SCP-06, CMP-03, CMP-04	Clinical representative and regulatory affairs
CLN-02	Existing-evidence relevance and limitations assessment.	CLN-01	Clinical representative
CLN-03	Clinical-evidence decision memorandum and conditional study planning brief.	CLN-02, CMP-07, TST-12	Clinical and regulatory functions
CLN-04	Clinical rationale and claim limitation record.	CLN-03, SCP-06	Clinical representative and regulatory affairs
LBL-01	Controlled IFU content master and indication consistency checklist.	SCP-03, SCP-04, SCP-06	Labeling function clinical and regulatory affairs
LBL-02	Device and package label-content master with identifier responsibilities.	SCP-02, REG-01	Labeling and quality assurance
LBL-03	Sterility and single-use label claim-to-evidence record.	TST-08, TST-09, SCP-06	Sterilization labeling and regulatory affairs

Record	Evidence output	Prerequisites	Responsible
LBL-04	Expiry storage and handling claim substantiation record.	TST-10, SCP-06	Packaging engineering and labeling
LBL-05	Prescription-labeling applicability and final wording decision.	SCP-03, LBL-01	Regulatory affairs and labeling
LBL-06	UDI applicability data and label-control plan.	REG-01, SCP-02	Regulatory operations and labeling
LBL-07	Visual symbol glossary and artwork applicability register.	SCP-06, STD-01	Labeling regulatory affairs and human factors
LBL-08	Final labeling review and revision-release record.	LBL-02, LBL-03, LBL-04, LBL-05, LBL-06, LBL-07, HFE-06	Quality assurance regulatory affairs and labeling
REG-01	Establishment and commercial-role applicability matrix.	SCP-01	Regulatory operations and quality assurance
REG-02	Foreign-establishment agent and importer applicability decisions.	REG-01	Regulatory operations
REG-03	Registration listing and maintenance plan with actual completion records when performed.	REG-01, REG-02, PTH-01	Regulatory operations and authorized account owner
REG-04	Commercial readiness and accountable release record.	REG-03, LBL-08, PMS-05	Quality assurance regulatory affairs and commercial operations
PMS-01	Complaint intake investigation and device traceability workflow.	QMS-04, SCP-02	Quality assurance and technical investigation functions
PMS-02	MDR applicability decision tree and reporting-clock controls.	PMS-01, REG-01	Regulatory reporting and quality assurance
PMS-03	Correction/removal and field-action decision workflow.	PMS-01, REG-01	Quality assurance regulatory affairs and commercial operations
PMS-04	Device-specific trend review and risk-feedback register.	PMS-01, QMS-04	Quality assurance risk management and regulatory affairs
PMS-05	Postmarket operational readiness and effectiveness record.	PMS-02, PMS-03, PMS-04	Quality assurance and regulatory operations

Record	Evidence output	Prerequisites	Responsible
CHG-01	Controlled baseline and change-request register.	SCP-01, SCP-02, SCP-03	Design engineering and quality assurance
CHG-02	Regulatory change and submission-impact assessment.	CHG-01, CLS-02, CMP-07	Regulatory affairs
CHG-03	Material process and validation impact matrix.	CHG-01, SCP-05, STD-04, STD-06	Materials biological safety sterilization and packaging functions
CHG-04	Use labeling and technology change-impact record.	CHG-01, HFE-02, LBL-01, SW-01, CYB-01	Human factors design and regulatory affairs
CHG-05	Change authorization implementation and effectiveness record.	CHG-02, CHG-03, CHG-04	Quality assurance with accountable technical and regulatory owners
DEC-01	Owned issue and decision register with evidence links.	SCP-01	Program lead regulatory affairs and quality assurance
DEC-02	Evidence closure and supported-claim decision record.	QMS-05, CMP-07, CLN-04, HFE-05	Regulatory affairs quality assurance and technical evidence owners
DEC-03	Exact demonstration-input and report release decision with artifact identities.	DEC-01, DEC-02, LBL-07	Owner and accountable report reviewers
EXE-01	Baseline and regulatory strategy milestone decision.	SCP-05, CLS-02, PTH-01, CMP-07, DEC-01	Program lead and regulatory affairs
EXE-02	Evaluated evidence and final-claim milestone review.	TST-12, QMS-05, DEC-02, LBL-08	Technical program lead quality assurance and regulatory affairs
EXE-03	Submission authorization FDA decision and commercial readiness milestone records.	SUB-06, REG-04, PMS-05	Regulatory affairs quality assurance and authorized commercial owners

Assessment provenance and limits

Input provenance: an independently authored fictional device profile. No customer technical file, real-device performance result or prior submission evidence is an assessment input.

Rule provenance: issue 48 profile-fidelity candidate. Public regulatory references identify the basis to review; a listed reference is not a claim that every conclusion, source edition or device-specific application has been approved. The report is profile-driven and does not claim a comprehensive review of uploaded technical-file contents.

Regulatory Basis

Key regulations, FDA materials, recognized-standards references, and supporting public-authority sources used to ground this strategy.

Regulation

- **Catheter introducer classification** — Electronic Code of Federal Regulations · Direct strategy basis
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-870/subpart-B/section-870.1340>
- **UDI data submission applicability** — Electronic Code of Federal Regulations · Direct strategy basis
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-830/subpart-E/section-830.300>
- **Manufacturer medical device reporting** — Electronic Code of Federal Regulations · Direct strategy basis
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-803/subpart-E/section-803.50>
- **Prescription device labeling** — Electronic Code of Federal Regulations · Direct strategy basis
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-801/subpart-D/section-801.109>
- **Reports of corrections and removals** — Electronic Code of Federal Regulations · Direct strategy basis
<https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-806/subpart-B/section-806.10>

FDA database

- **FDA product classification record DYB** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=DYB>
- **FDA recognized consensus standards database** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>
- **FDA recognition 5-148 for ISO 15223-1** — U.S. Food and Drug Administration · Direct strategy basis
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard_identification_no=46534

FDA guidance / information

- **FDA nonclinical bench performance report guidance** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket>
- **FDA substantial equivalence guidance** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k>
- **FDA human factors submission content guidance** — U.S. Food and Drug Administration · Direct strategy basis

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-human-factors-information-medical-device-marketing-submissions>

- **FDA biological evaluation guidance** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- **Premarket notification 510(k)** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k>
- **FDA eSTAR program** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program>
- **Role-specific registration and listing** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/medical-devices/device-registration-and-listing/who-must-register-list-and-pay-fee>
- **FDA sterility information guidance** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/submission-and-review-sterility-information-premarket-notification-510k-submissions-devices-labeled>
- **Quality Management System Regulation** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
- **FDA use of symbols in labeling** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling>
- **FDA human factors engineering guidance** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices>
- **Appropriate use of voluntary consensus standards** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>
- **FDA labeling symbols questions and answers** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/medical-devices/device-labeling/use-symbols-labeling-frequently-asked-questions>
- **Medical device reporting** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities>
- **Corrections and removals** — U.S. Food and Drug Administration · Direct strategy basis
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>

Consensus standard publisher

- **ISO 11070 public catalogue metadata** — www.iso.org · Direct strategy basis
<https://www.iso.org/standard/63315.html>