

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

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

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.

- 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.

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

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>

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.

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