



September 24, 2025

Surmodics, Inc.
Peter Bather
Staff Regulatory Affairs Associate
7905 Golden Triangle Drive
Eden Prairie, Minnesota 55443

Re: K252227

Trade/Device Name: Pounce™ Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 22, 2025
Received: August 25, 2025

Dear Peter Bather:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Misti L. Malone -S

Misti Malone, PhD

Assistant Director

DHT2C: Division of Coronary and
Peripheral Intervention Devices

OHT2: Office of Cardiovascular Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (*if known*)
K252227

Device Name
Pounce™ Sheath

Indications for Use (*Describe*)

The Pounce™ Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature.

Type of Use (*Select one or both, as applicable*)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Pounce Sheath 16Fr Special 510(k) Summary

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510(k) Summary

Date Prepared: 16 July 2025

510(k) Submitter Name / Contact Person:

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510(k) Submitter Establishment Registration Number:

3014687026

Device General Information

Trade Name	Pounce™ Sheath
Common Name	Catheter Introducer
Classification Information	Catheter Introducer pursuant to 21 CFR 870.1340, Class II
Product Code	DYB
Device Panel	Cardiovascular
Predicate Device	Pounce™ Sheath 510(k)#: K231828
Common Name	Catheter Introducer

Device Description

The Pounce™ Sheath 16Fr is a single-use, sterile introducer sheath intended for the introduction of therapeutic or diagnostic devices within the vasculature. The Pounce™ Sheath 16Fr includes the following features:

- Braided nitinol, self-expanding funnel at the sheath's distal end
- Handle assembly with slider button to actuate the funnel's deployment
- Hub and hemostasis valve assembly to allow for device introduction and removal
- Aspiration assembly including tubing, a stopcock, and connection for a 60 cc syringe

Additional components provided within the packaging include:

- 0.035" guidewire compatible pre-dilator for access site preparation
- 0.035" guidewire compatible dilator designed for atraumatic introduction of the sheath
- 60 cc locking syringe, compatible with the sheath's aspiration assembly

A radiopaque marker band is located at the distal tip of the sheath during introduction and removal, when the funnel is sheathed. When the funnel is unsheathed, the radiopaque marker band is located proximally to the funnel. The funnel is sheathed and unsheathed with the actuation of a slider button located on the handle assembly. The hemostasis valve can be actively defeated (opened), during device introduction or removal, by pressing down on the base of the surrounding hub. This action is designed to minimize device contact across the hemostatic valve during the introduction or removal of devices. The aspiration assembly also aids in the delivery of contrast or saline.

Indication for Use

The Pounce™ Sheath is intended to introduce therapeutic or diagnostic devices into the vasculature.

Comparison of Technological Characteristics

The Pounce Sheath 16Fr is substantially equivalent to the predicate Pounce Sheath (K231828) in design, intended use, principles of use, biocompatibility, sterility, and labeling. The Pounce Sheath 16Fr has the same fundamental scientific technology as the predicate; the modifications in the Pounce Sheath 16Fr are limited to an increased sheath diameter (from 12Fr to 16Fr), the addition of an 18Fr pre-dilator to facilitate initial vessel dilation prior to sheath insertion, and some minor material changes. The minor dimensional and component changes introduced have been fully verified through performance bench and biocompatibility testing and determined to be substantially equivalent.

Substantial Equivalence and Summary of Studies

The Pounce Sheath 16Fr is substantially equivalent to the predicate device based on the indications for use, technological characteristics, and principles of use. Results of successful design verification and biocompatibility testing demonstrate the substantially equivalent safety and effectiveness of the Pounce Sheath and that the minor dimensional and component changes identified do not raise new questions of safety or effectiveness compared to the predicate device. All tests met documented acceptance criteria.

- **Performance / Verification Bench Testing** - The Pounce Sheath 16Fr has been evaluated through the following tests:
 - Dimensional (Working Length, ID, OD, Funnel Length)
 - Funnel Radial Force
 - Funnel Column Strength
 - Insertion Force (Sheath and Pre-Dilator)
 - Dilator Withdrawal Force
 - Shaft Flexibility (Sheath and Dilator)
 - Simulated Use
 - Funnel Deployment and Retraction Force
 - Sheath Lock Action Force
 - Hemostasis Valve Leakage
 - Hemostasis Valve Defeater Action/Force
 - Aspiration Pathway
 - Kink Radius
 - Torque Strength
 - Tensile Strength
 - Liquid and Air Leakage
 - Atraumatic Surfaces/Tips
 - Radiopacity (Sheath and Dilators)
 - Corrosion
 - Dilator and Pre-Dilator Hub Compatibility
 - Dilator Lock Force
 - Clean Surface
 - Packaging integrity testing
- **Biocompatibility** - Biocompatibility of the Pounce Sheath 16Fr has been evaluated in accordance with ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” and FDA Guidance “Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, Guidance for Industry and Food and Drug Administration Staff”. Per the requirements of ISO 10993-1 the Pounce Sheath is classified as an externally communicating device in contact with circulating blood for limited exposure duration. Biocompatibility tests appropriate for the device classification were selected, and testing was completed in accordance with FDA Good Laboratory Practice (GLP) regulations (21 CFR, Part 58). All biocompatibility test results met documented acceptance criteria and did not raise any questions regarding biological safety. The following biocompatibility tests were performed:
 - Cytotoxicity
 - Irritation / Intracutaneous Reactivity
 - Sensitization
 - Acute Systemic Toxicity
 - Material Mediated Pyrogenicity
 - Hemocompatibility
 - ASTM Hemolysis Assay

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- SC5b Complement Activation Assay
- Partial Thromboplastin Time (PTT)
- Heparinized Platelet and Leukocyte Count Assay
- *In Vivo* Thrombogenicity