September 7, 2023

Surmodics, Inc.
Peter Bather
Sr. Regulatory Affairs Associate
7905 Golden Triangle Dr. Ste. 190
Eden Prairie, Minnesota 55344

Re: K231828
Trade/Device Name: Pounce™ Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 21, 2023
Received: June 22, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231828

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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510(K) Summary

Date Prepared: June 21, 2023
Submitters Name / Contact Person

General Information	
Trade Name:	Pounce™ Sheath
Common / Usual Name:	Catheter Introducer
Regulatory Classification:	Class II
Product Code:	DYB
Device Panel:	Cardiovascular
Predicate Device:	Cook Performer Introducer K171999
Reference Device:	Inari ClotTriever Sheath (device in ClotTriever Thrombectomy System) K210689.

Device Description

The Pounce™ Sheath is a single-use, sterile introducer sheath intended for the introduction of therapeutic or diagnostic devices within the vasculature. The Pounce™ Sheath 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 to include tubing, a stopcock, and connection for a 60 cc syringe

Additional components provided within the packaging include:

- 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), prior to 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.

Intended Use

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

Comparison of Technological Characteristics

The Pounce Sheath is similar to the legally marketed predicate device (Cook Performer Introducer, K171999) in design, indications for use, principles of use, materials, and sterility. The Pounce sheath and the predicate device are intended to introduce therapeutic or diagnostic devices into the vasculature. Differences in the principles of use and technological characteristics from the predicate device are limited to the use of the distal wire funnel feature, which is the same as the reference device (Inari ClotTriever Sheath, K210689).

Substantial Equivalence and Summary of Studies

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

The subject device has been evaluated through the following categories of testing.

- Performance Bench Testing
- Biocompatibility
- Sterilization

Performance Bench Testing

The Pounce Sheath has been evaluated through the following tests:

- Dimensional (Working Length, ID, OD, Funnel Length)
- Funnel Radial Force
- Funnel Column Strength
- Insertion Force
- Dilator Withdrawal Force
- Shaft Flexibility (Sheath and Dilator)
- Simulated Use
- Funnel Deployment/Retraction Force
- Funnel Sheath Lock Action/Force
- Hemostasis Valve Leakage

- Hemostasis Valve Defeater Action/Force
- Aspiration Pathway
- Kink Radius
- Torque Strength
- Tensile Strength
- Syringe Connection and Connector Strength
- Liquid Leakage
- Air Leakage
- Atraumatic Surfaces/Tips
- Radiopacity
- Stopcock Luer Defeatable Valve Compatibility
- Dilator Hub Compatibility
- Stopcock Open Force
- Dilator Locking Force
- Device Markings
- Clean Surface
- Corrosion Resistance

Biocompatibility

Biocompatibility of the Pounce Sheath 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). The following biocompatibility tests were performed in accordance with ISO 10993-1:

- Cytotoxicity
- Irritation / Intracutaneous Reactivity
- Sensitization
- Acute Systemic Toxicity
- Material Mediated Pyrogenicity
- Hemocompatibility
    - ASTM Hemolysis Assay
    - SC5b Complement Activation Assay
    - Partial Thromboplastin Time (PTT)
    - Heparinized Platelet and Leukocyte Count Assay
    - *In Vivo* Thrombogenicity

All test results met documented acceptance criteria.

Sterilization

The results of the sterilization product testing have demonstrated that the Ethylene Oxide (EtO) sterilization method for the Pounce Sheath meets the requirements of ISO 11135.

Animal Testing

No animal testing data was required for the Pounce Sheath.

Clinical Data

No clinical data was required for the Pounce Sheath.

Conclusions

Based upon the device description, intended use, technological characteristics & performance data it can be concluded that the Pounce Sheath is substantially equivalent to the predicate device.