September 11, 2024

Surmodics Inc.
Holly Ramirez
Sr. Staff Regulatory Affairs Specialist
7905 Golden Triangle Dr. Ste. 190
Eden Prairie, Minnesota 55344

Re: K241362
Trade/Device Name: Pounce XL Thrombectomy System (PTS-1011-7F135)
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: August 6, 2024
Received: August 6, 2024

Dear Holly Ramirez:

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,

Ariel G. Ash-shakoor -S

Digitally signed by Ariel G. Ash-shakoor -S
Date: 2024.09.11 12:01:22 -04'00'

For

Gregory O'Connell
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241362

Device Name

Pounce XL Thrombectomy System (PTS-1011-7F135)

Indications for Use *(Describe)*

The Pounce Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

SURMODICS

Date Prepared: 5/13/2024

Submitters Name / Contact Person

510k Submitter Address
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General Information	
Trade Name:	**Pounce™ XL Thrombectomy System (PTS-1011-7F135)**
Common / Usual Name:	Thrombectomy Catheter
Classification:	Class II
Product Code:	QEW 21 CFR 870.5150
Predicate Devices:	K220501 Pounce™ Thrombectomy System
	K231022 Pounce™ LP Thrombectomy System

Device Description

The Surmodics™ Pounce™ XL Thrombectomy System is a percutaneous catheter system designed to facilitate mechanical thrombus removal in the peripheral arterial vasculature. The system is comprised of three separate components: a delivery catheter, a basket wire and a funnel catheter. The system also includes a basket loading tool accessory for loading the basket wire into the delivery catheter. The system contains the necessary radiopaque components to conduct the procedure and the system should be introduced through a minimum 7 Fr guide sheath.

The Delivery Catheter is flexible and designed to deliver the Basket Wire to the location of the thrombus. Incorporated in the catheter is a radiopaque marker band located at the distal tip.

The Basket Wire is comprised of two distal self-expanding baskets mounted on a core wire for capturing thrombus. The distal capture baskets have integral radiopaque markers mounted on the struts of the basket for basket visibility under fluoroscopy.

The Funnel Catheter is used for thrombus collection and retrieval in conjunction with the Basket Wire. The Funnel Catheter is comprised of an inner funnel catheter and an outer delivery catheter. The two catheters work together to allow unsheathing and sheathing of the funnel using the slider button on the integrated handle.

Intended Use / Indications for Use

The Pounce™ Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature.

Comparison of Technological Characteristics

The Pounce XL Thrombectomy System is substantially equivalent to the previous Pounce Thrombectomy Systems (K220501, K231022) in design, intended use, principles of use, biocompatibility, sterility, and labeling. This new 510(k) are to extends the product line to include use in vessels ranging from 5.5 mm – 10 mm. The larger basket and funnel components have been verified through performance bench, animal, and biocompatibility testing and determined to be substantially equivalent.

Substantial Equivalence and Summary of Studies

Results of design verification testing demonstrate that the technological differences identified do not raise new questions of safety or effectiveness compared to the predicate device. The Pounce XL Thrombectomy System is substantially equivalent to the predicate device based on intended use and technological characteristics. The subject device has been evaluated through the following tests:

- Dimensional evaluations
- Radiopacity
- Tensile Strength
- Freedom from leakage
- Hub/Luer connector compatibility
- Removal Force
- Basket Wire Fatigue
- Kink Resistance
- Radial Force
- Torque Strength
- Ancillary Device Compatibility
- Atraumatic Surfaces
- Simulated Use
- Biocompatibility

All test results met documented acceptance criteria and did not raise new questions of safety or effectiveness. The Pounce XL Thrombectomy System is substantially equivalent to the predicate device.