March 23, 2022

Surmodics Inc.
Holly Ramirez
Senior Staff Regulatory Affairs Specialist
7905 Golden Triangle Drive Suite 190
Eden Prairie, Minnesota 55344

Re: K220501
Trade/Device Name: Pounce Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: February 21, 2022
Received: February 22, 2022

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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220501

Device Name
Pounce™ Thrombectomy System

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.

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510(k) Summary

Date Prepared: 18 March 2022

Submitters Name/Contact Person

510K Submitter and Contact for Routine Correspondence

Holly Ramirez
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510k Submitter Establishment Registration Number

3014687026

General Information	
Trade Name:	Pounce™ Thrombectomy System
Common / Usual Name:	Thrombectomy Catheter
Classification Name	Embolectomy Catheter
Regulation/Product Code	21 CFR 870.5150
Device Panel	Cardiovascular
Regulatory Classification:	Class II
Product Code:	QEW
Predicate Device:	Pounce™ Thrombectomy System (K211492)

1 Device Description

The Surmodics Pounce™ 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 with a preloaded loading tool, and the Funnel Catheter. The system contains radiopaque components to conduct the procedure and is intended to be introduced through a minimum 7Fr guide sheath.

The Delivery Catheter is a flexible 5Fr catheter 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 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.

2 Indication for Use

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

3 Comparison of Technological Characteristics

The Pounce Thrombectomy System is substantially equivalent to the previous Pounce Thrombectomy System (K211492) in design, intended use, principles of use, biocompatibility, sterility, and labeling. Changes to the predicate device that have led to the submission of this new 510(k) are ergonomic and branding in nature, including a new handle design, new packaging to accommodate the handle, and updated coloring. All characteristics that were not identical to the predicate device were verified through performance bench and biocompatibility testing and determined to be substantially equivalent.

4 Performance Bench Testing

Results of design verification and biocompatibility testing demonstrates that the technological and material differences identified do not raise new questions of safety or effectiveness compared to the predicate device. The Pounce Thrombectomy System has been evaluated through the following tests:

- Dimensional
- Tensile Strength
- Air and Liquid Leak
- Handle Split Force
- Retention Force
- Atraumatic Surfaces
- Assembled Functionality
- Torque Strength
- Lock and Unlock Force
- Tensile Strength
- Packaging/Distribution
- Biocompatibility

5 Clinical Studies and Testing

No clinical studies were required for the Pounce Thrombectomy System.

6 Conclusion

Based on the device description, materials, technological characteristics, and accompanying performance and biocompatibility data it can be concluded that the device modifications made to the Pounce Thrombectomy System are substantially equivalent to the predicate device and the device will continue to function per its intended use.