July 30, 2021

Surmodics, Inc.
Holly Ramirez
Senior Principal Regulatory Affairs Specialist
9924 W 74th Street
Eden Prairie, Minnesota 55344

Re: K211492
Trade/Device Name: Pounce™ Thrombectomy System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEW
Dated: June 9, 2021
Received: June 10, 2021

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)*
K211492

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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SURMODICS

Pounce™ Thrombectomy System 510(k) Summary

SUBMITTER [807.92(a)(1)]

Submitter's Name: Surmodics, Inc.

Address: 9924 W 74th St, Eden Prairie MN 55344

Contact Person: Holly Ramirez

Telephone: 952-500-7545

Email: hramirez@surmodics.com

Date Prepared: May 12, 2021

DEVICE [807.92(a)(2)]	
Trade Name:	Pounce™ Thrombectomy System
Common Name:	Thrombectomy catheter
Regulation Name:	Embolectomy catheter
Regulation Number:	21 CFR 870.5150
Classification:	Class II
Product Code:	QEW
Review Panel:	Cardiovascular
PREDICATE [807.92(a)(3)]	Predicate Device: Pounce™ Thrombectomy System (K192814)

DEVICE DESCRIPTION [807.92(a)(4)]

The 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 5Fr Basket Delivery Catheter, a Basket Wire Assembly, and a Trumpet Assembly. The system also includes a Basket Loading Tool accessory for loading the Basket Wire Assembly into the Basket Delivery Catheter. The system contains the necessary radiopaque components to conduct the procedure and the system should be introduced through a minimum 7Fr guide sheath.

The Basket Delivery Catheter is a flexible 5Fr catheter designed to deliver the Basket Wire Assembly to the location of the thrombus.

The Basket Wire Assembly is comprised of two distal self-expanding baskets mounted in series on a wire for capturing thrombus.

The Trumpet Assembly is used for thrombus collection and retrieval. The Trumpet Assembly is made of an

inner trumpet catheter and an outer trumpet delivery catheter. The two catheters work together to allow deployment and retraction of the trumpet feature.

INDICATION FOR USE [807.92(a)(5)]
The Pounce™ Thrombectomy System is intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature.

PREDICATE DEVICE COMPARISON [807.92(a)(6)]
The subject and predicate device are both intended for non-surgical removal of thrombi and emboli from the peripheral arterial vasculature, and they have the same technological characteristics. The only difference is a revised contraindication for the smaller native vessel size from 4.5 mm to 3.5 mm.

NONCLINICAL PERFORMANCE TESTING SUMMARY [807.92(b)]
Based on the outcome of design control and risk assessment activities the following non-clinical bench testing was conducted to evaluate the performance of the Pounce™ Thrombectomy System:

- Basket Cage Radial Force
- Thrombectomy System Simulated Use

Test results demonstrated that all pre-defined acceptance criteria were met. Therefore, the device conforms to established product specifications and intended use and no new questions of safety and effectiveness were raised.

Animal Testing:
Animal testing previously submitted as part of K192814 was also utilized to demonstrate substantial equivalence.

Clinical Data:
No clinical data was required to demonstrate substantial equivalence.

Conclusions:
Based on the risk assessment and subsequent design verification testing mitigations it is concluded that revising the contraindication did not impact the safety or effectiveness of the Pounce Thrombectomy System and it is substantially equivalent to the predicate device.