September 21, 2020

Surmodics, Inc.
Amy Yanta
Regulatory Affairs
9924 West 74th Street
Eden Prairie, Minnesota 55344

Re: K192814
Trade/Device Name: Pounce™ Thrombus Retrieval System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: QEW
Dated: August 14, 2020
Received: August 17, 2020

Dear Amy Yanta:

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)*
K192814

Device Name
Pounce™ Thrombus Retrieval System

Indications for Use *(Describe)*
The Thrombus Retrieval System is intended for the non-surgical removal of thrombi and emboli from the arterial peripheral 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

510(k) Summary - K192814

Date Prepared: September 18, 2020

Submitters Name / Contact Person

510k Submitter Address

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General Information	
Trade Name:	Pounce™ Thrombus Retrieval System
Common name:	Thrombectomy catheter
Classification name:	Embolectomy catheter
Regulation Number:	21 CFR 870.5150
Classification:	Class II
Product Code:	QEW
Review Panel:	Cardiovascular
Predicate Devices:	1. Predicate Device: NexGen Peripheral Mechanical Retrieval Device (K110315) 2. Reference device: NexGen Peripheral Expandable Catheter (K102925)

Device Description

The Pounce™ Thrombus Retrieval 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 (distal 30 cm) catheter designed to deliver the Basket Wire Assembly to the location of the thrombus. Incorporated in the catheter is a radiopaque marker band located approximately 3 mm from the distal tip.

The Basket Wire Assembly is comprised of two distal nitinol self-expanding baskets mounted in series on a 0.026" diameter nitinol core wire for capturing thrombus. Unconstrained, both baskets are 6 mm in diameter. The core-wire is tapered on the distal end with a safety coil for atraumatic delivery. The distal capture baskets have integral radiopaque markers mounted on the struts of the basket. The Basket Wire Assembly also comes with a Basket Loading Tool for easy loading into the Basket Delivery Catheter.

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. The trumpet feature is made of soft, self-expanding nitinol that has integrated radiopaque wires for enhanced visualization. Unconstrained, the nitinol trumpet is 7 mm in diameter. The two-catheter device is manipulated at the proximal end using dual Tuohy-Borst adapters.

Indications for Use/Intended Use
The Thrombus Retrieval System is intended for the non-surgical removal of thrombi and emboli from the arterial peripheral vasculature.

Comparison of Technological Characteristics

The Pounce™ Thrombus Retrieval System is equivalent to the legally marketed predicate and reference devices in principles of use, design, and materials. The Thrombus Retrieval System and the predicate and reference devices are both intended for non-surgical removal of thrombi and emboli from the peripheral arterial vasculature and share the same device classification.

Surmodics Thrombus Retrieval System and Predicate(s) Comparison:

	Pounce™ Thrombus Retrieval System		**Predicate Device**	**Reference Device**
			The NexGen Mechanical Retrieval Device (MRD) (K110315)	**NexGen Peripheral Expandable Catheter (K102925)**
Device Component	Basket Wire Assembly	Trumpet Assembly	Coil (wire assembly)	Expandable Catheter
Deployment Mechanism	Inserted into 5F Catheter Operator Controlled – linear actuation	Loaded onto proximal end of Basket Wire Operator Controlled – linear actuation	Inserted into 4F Guide Catheter Operator Controlled – linear actuation	Inserted over guidewire into 8F guide catheter Operator Controlled – linear actuation
Material	Nitinol, Platinum/Iridium, Platinum/Tungsten Guide/Delivery Catheter: HDPE, Platinum/Iridium	Pebax, HDPE and Nitinol	Stainless Steel, Polymer, Nitinol, and Platinum Alloy	Pebax, HDPE and Nitinol

	Pounce™ Thrombus Retrieval System		Predicate Device	Reference Device
			The NexGen Mechanical Retrieval Device (MRD) (K110315)	NexGen Peripheral Expandable Catheter (K102925)
Guidewire Compatibility	Guide/Delivery Catheter: 0.035"	Uses the Basket Wire for deployment (0.26")	.035"	.035"
Deployed Diameter	Baskets: 6mm	Trumpet: 7mm	Loop Coil: 12 mm	Funnel: 5mm, 7mm, 9mm, 11mm
Working Lengths	140cm	120cm	125 cm	43cm and 116cm
Principals of Use	Guide/Delivery Catheter and basket wire are deployed distal to the occlusion. Guide/Delivery Catheter is withdrawn as the basket wire Baskets are released distal to occlusion and capturing the embolic material for removal as baskets are retracted back.	Trumpet assembly is proximally loaded onto basket wire and into guide sheath until beyond the tip of guide sheath. While holding the proximal Tuohy-borst (TB) valve, the distal TB valve is retracted back to unsheathe the trumpet.	Guide Catheter and Coil wire are deployed distal to the occlusion. Guide catheter is withdrawn as the MRD coils are released distal to occlusion and enmeshing the embolic material for removal as coils are retracted back.	Expandable catheter is inserted over guidewire into the guide catheter until flush with the guide catheter tip. Retraction of the guide catheter deploys the expandable nitinol encapsulatory.
Intended Use / Indications	The Thrombus Retrieval System is intended for the non-surgical removal of thrombi and emboli from the arterial peripheral vasculature.		The NexGen Mechanical Retrieval Device (MRD) is indicated for the removal of embolic/thrombotic material, including thrombus and debris, from peripheral arteries and veins, peripheral bypass grafts, and the removal of thrombus from clotted synthetic dialysis grafts and arterio-venous fistulas.	The NexGen Peripheral Expandable Catheter is indicated for the percutaneous access to the peripheral vascular system and is designed to assist in the placement and removal of devices. This device is not intended for use in the coronary or cerebral vasculature.

Assessment of Differences

Technological differences between the Surmodics Thrombus Retrieval System and the predicate

devices are listed below.

- Device Materials: The Surmodics basket material is Nitinol while the NexGen (K110315) coil material is Stainless-Steel. The superelastic Nitinol material used for the baskets allows them to be collapsed and deployed multiple times while retaining their shape.
- Thrombi/emboli capture device Dimensions: The Surmodics basket deployment diameter is 6mm while the NexGen (K110315) loop coils have a deployed diameter of 12mm. Surmodics specifically defines the vessel size the Thrombus Retrieval System is compatible for use with.
- Configuration: The Surmodics Thrombus Retrieval System linear actuation utilizes Tuohy-Borst (TB) Valves as the user interface for the push/pull of the device components by the user. The NexGen Retrieval Device (MRD) (K110315) linear actuation utilizes a retractor handle to retract the nitinol pull wire, which actuates the coil. The TB valves enable the user to perform flushing through side ports, sealing of the components, and locking of the system components as needed during the procedure.
- Intended use/Indications: The Thrombus Retreival System and Predicate device (K11035) have similar intended use for the use of removal of emboli and thrombi in the arterial peripheral vasculature. The predicate adds additional use in viens, grafts, and fistulas.

Potential risks posed by the Thrombus Retrieval System were evaluated in a risk analysis process compliant with ISO 14971 *Medical Devices – Application of Risk Management to Medical Devices*. The potential hazards identified in the risk analysis, their causes, and the mitigation measures and related verification are identified in the risk documentation. The dimensional differences of the thrombi/emboli capture devices of the Thrombus Retrieval System and the NexGen predicate (K110315) are insignificant due to the different vessel sizes each has claimed compatibility with and does not change the similar functions of each. Additionally, design and packaging verification testing was completed and demonstrates the Thrombus Retrieval System meets the design requirements.

Results of the risk analysis demonstrated that following risk mitigation, the identified potential hazards are considered acceptable (low risk) in all instances.

Substantial Equivalence and Summary of Studies

The Thrombus Retrieval System is substantially equivalent to the predicate and reference devices based on intended use/indications for use, technological characteristics and principles of use. Based on the results of successful design verification testing, the Pounce Thrombus Retrieval System was shown to be substantially equivalent to the predicate device and any technological differences between the Pounce Thrombus Retrieval System and the predicate and reference devices did not raise new questions of safety or effectiveness. All test results met documented acceptance criteria and/or included justification of values. The subject device has been evaluated through the following performance bench testing:

- Liquid leak
- Air leak
- Visual Inspection
- Simulated Use
- Corrosion
- Trackability
- Tip pull
- Burst
- Tensile
- Hemostasis valve lock
- Particulate
- Radiopacity
- Visual
- Dimensional
- Kink
- Radial force
- Tip Flexibility
- Flushability
- Component compatibility
- Hemostasis valve leak
- Luer connection
- Torque

Packaging testing was successfully performed in accordance with ISO 11607-1 and included:

- Visual inspection
- Seal Strength
- Bubble leak
- Environmental monitoring
- Distribution simulation

Biocompatibility tests were performed in accordance with ISO 10993-1 and included:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity (acute)
- Hemocompatibility
- Pyrogenicity
- Chemical characterization

Sterilization evaluation demonstrated that the Ethylene Oxide (EtO) sterilization method for the Thrombus Retrieval System meets the requirements of ISO 11135 and sterility of the system will be maintained over the entirety of the shelf life.

Animal Testing:

The Thrombus Retrieval System device was subjected to an acute animal GLP study to evaluate and confirm the substantially equivalent performance and safety of the Pounce Thrombus Retrieval System device use within an arterial vasculature system.

Clinical Data:

No Clinical data is being submitted for the Thrombus Retrieval System.

Conclusions:

Based upon the device indications for use, technological characteristics and performance data it can be concluded that the Thrombus Retrieval system is substantially equivalent to the predicate and reference devices and is appropriate for the indications for use.