January 17, 2020

Merit Medical Systems, Inc.
Michael O'Sullivan
Senior Regulatory Affairs Specialist
Parkmore Business Park West
Galway, IE Galway

Re: K193507
Trade/Device Name: ONE Snare™ endovascular snare system
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: December 13, 2019
Received: December 18, 2019

Dear Michael O'Sullivan:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193507

Device Name
ONE Snare endovascular snare system

Indications for Use *(Describe)*
The ONE Snare endovascular snare system is intended for use in the coronary and peripheral vascular system or hollow viscous to retrieve and manipulate foreign objects. Retrieval and manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.

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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Section 5
510(k) Summary

General Provisions	Submitter Name: Merit Medical Systems, Inc. Address: 1600 West Merit Parkway South Jordan, UT 84095 Telephone Number: (+353) 91 703700 (3061) Fax Number: (+353) 91 680 104 Contact Person: Mark Mullaney Registration Number: 1721504 Correspondent Name: Merit Medical Ireland Ltd. Address: Parkmore Business Park West Galway, Ireland Telephone Number: (+353) 91 703700 (3224) Fax Number: (+353) 91 680 104 Contact Person: Michael O'Sullivan Date of Preparation: Jan 17th 2020 Registration Number: 9616662 510(k) Number: K193507
Subject Device	Trade Name: ONE Snare® Common/Usual Name: One Snare Endovascular Snare System Classification Name: 21 CFR 870.5150 Device percutaneous retrieval
Predicate Device	**Premarket Notification Predicate: (Primary Predicate)** Trade Name: Merit One Snare Endovascular Snare System Classification Name: 21 CFR 870.5150 Premarket Notification: K122088 Manufacturer: Merit Medical Systems, Inc.
Classification	Class II 21 CFR 870.5150 Device percutaneous retrieval FDA Product Code: MMX Review Panel: Division of Cardiovascular Devices
Intended Use	The ONE Snare endovascular snare system is intended for use in the coronary and peripheral vascular system or hollow viscous to retrieve and manipulate foreign objects. Retrieval and manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access venipuncture procedure assistance.
Indications for Use	The ONE Snare endovascular snare system is intended for use in the coronary and peripheral vascular system or hollow viscous to retrieve and manipulate foreign objects. Retrieval and manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin

	sheath stripping, and central venous access venipuncture procedure assistance.
Device Description	The ONE Snare Endovascular Snare System is a snare system that is designed for use in the coronary and peripheral vascular system or hollow viscous to retrieve and manipulate foreign objects. The One Snare wire consists of a Nitinol core with a ground tapered distal section, a formed nitinol cable covered with a gold-plated tungsten coil. The formed cable with coil is attached to the core wire and then covered with a PTFE polymer sleeve. The wires are packaged with an introducer, torque device and guiding catheter – this makes up the "One Snare Endovascular Snare System".
Comparison to Predicate	The proposed new configuration will consist of the following • snare with a 15mm loop diameter which will be 80cm in length. The loop diameter and length fall within the existing approved range for the ONE Snare (Snare loop diameter ranges from 5mm-35mm and Snare length ranges from 65cm-200cm.) Snare dimensions are as follows: 4F, 80cm, 15mm loop. • catheter modified with a 15+/-5 degree angle at the catheter tip. The angle will be 1cm from the distal tip. Catheter dimensions: 4F, 65cm, Marker-Banded, with 1cm of the distal tip being angled 15+/-5 degrees. None of the above changes would be deemed sufficient to affect the technological characteristics of the device and thus the subject One Snare Endovascular Snare System is substantially equivalent to Predicate Device, the Merit ONE Snare Endovascular Snare K122088. The Indications for use of the subject wire are identical to Predicate Device.
Safety & Performance Tests	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests performed on the One Snare Endovascular Snare System were designed to demonstrate that the device meets critical design specifications as well as clinical performance attributes for its intended use. Where appropriate, the tests were based on the requirements of the following documents: • ISO 11070 - Sterile, single-use intravascular catheter introducers • ISO 11135 - Sterilization of health care products- Ethylene oxide-Requirements for development, validation and routine control of a sterilization process for medical devices processes • EN556 - Sterilization of medical devices - Requirements for terminally sterilized medical devices to be labeled "Sterile" • ISO 10555-1 - Intravascular Catheters – Sterile and Single-Use Catheters – Part 1: General Requirements The ONE Snare Endovascular Snare System was compared to the predicate device for various performance attributes that support substantial equivalence of the device. The difference in assembly between

	the modified device and the cleared device, Merit One Snare Endovascular Snare System [K122088] has raised no new issues with respect to the device. The following is a list of all testing that was successfully completed: • Snare Size Designation • Catheter Size Designation • Catheter Surface Inspection • Catheter OD Inspection • Catheter Tip Length of Angle • Catheter Angle • Catheter Tip ID Inspection • Simulated Use (design validation) All test results were comparable to the predicate devices and the subject One Snare Endovascular Snare System met the predeterminded acceptance criteria. This has demonstrated that the subject device is substantially equivalent to the predicate device.
Summary of Substantial Equivalence	Based on the Indications for Use, design, safety and performance testing, the subject One Snare Endovascular Snare System is substantially equivalent to the cleared Predicate Device, the Merit One Snare Endovascular Snare System [K122088].