



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 1, 2015

Merit Medical Systems, Inc.
Siobhan King
Senior Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K151497

Trade/Device Name: EN Snare Endovascular Snare System
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: MMX
Dated: June 2, 2015
Received: June 4, 2015

Dear Siobhan King:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "M. Zuckerman". The signature is written in a cursive style and is positioned above the typed name of the signatory.

for

Bram Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Merit Medical Systems, Inc.
Merit EN Snare Endovascular Snare System
Special Premarket Notification 510(k)

Section 4
Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Indications for Use	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.
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510(k) Number (if known)
K151497

Device Name
EN Snare Endovascular Snare System

Indications for Use (Describe)
 The EN 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.

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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**Section 5
510(k) Summary**

General Provisions

Submitter Name: Merit Medical Systems, Inc.
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Galway, Ireland
Telephone Number: (+353) 91 703700 (3052)
Fax Number: (+353) 91 703772
Contact Person: Siobhan King
Date of Preparation: 17 June 2015
Registration Number: 9616662

Subject Device

Trade Name: EN Snare Endovascular Snare System
Common/Usual Name: Device, Percutaneous Retrieval
Classification Name: Device, Percutaneous Retrieval

Predicate Device

Primary Predicate Device #1:
Trade Name: EN Snare Endovascular Snare System
Classification Name: Device, Percutaneous Retrieval
Premarket Notification: K092343
Manufacturer: Merit Medical Systems, Inc.

Reference Device #2:
Trade Name: ONE Snare System
Classification Name: Percutaneous retrieval device
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 EN 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	<p>The EN Snare Endovascular Snare System consists of four individual components: snare; catheter; insertion tool and torque device. Systems are available in various sizes and lengths. The snare is comprised of 3 interlaced stranded cables of platinum and super-elastic nitinol that form 3 loops and are mechanically secured with a crimp collar to a nitinol shaft wire. The super-elastic nitinol construction enables the loops of the snare to be introduced through a catheter without the risk of deformation. The catheter is manufactured with a Pebax outer layer and a PTFE inner layer with an embedded iridium/platinum markerband at the distal end, a Pebax hub and a polycarbonate luer. A snare insertion tool is also included for optional back-end loading of the snare into a preplaced catheter. The snare insertion tool is manufactured from polypropylene. The snare is inserted into an intravascular catheter and manipulated by use of an external torque device. The snare is offered in sizes ranging from 2mm to 45mm, with catheter sizes of 3.2F, 6F, and 7F.</p>
Comparison to Predicate	<p>The technological characteristics of the subject Merit EN Snare Endovascular Snare System are substantially equivalent to the Primary Predicate Device#1 Merit EN Snare Endovascular Snare System (K092343), and the Reference Device#2, Merit ONE Snare System, 510(k), K122088, for the following performance data – Corrosion Testing, Luer Testing and Packaging Testing. The difference between the subject Merit EN Snare Endovascular Snare System and the Primary Predicate Device#1 Merit EN Snare Endovascular Snare System (K092343) relates to a modification to the catheter and insertion tool design and materials only. The snare device and the torque device remain unchanged. While the intended use remains unchanged the indications for use are being clarified.</p>
Safety & Performance Tests	<p>No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Merit EN Snare Endovascular Snare System was conducted based on risk analysis. A battery of testing was conducted in accordance with protocols based on requirements outlined in guidance's and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.</p> <p>Where appropriate, the tests were based on the requirements of the following documents:</p> <ul style="list-style-type: none"> • FDA guidance Coronary and Cerebrovascular Guide Wire Guidance January 1995. • ISO 10555-1 2013 <i>Intravascular catheters – Sterile and single use catheters - Part 1: General Requirements.</i> • ISO 594-1:1986 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1: General requirements • ISO 594-2:1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – part 2: Lock fittings • ISO 11135:2014 <i>Sterilization of health care products-Ethylene oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices.</i> • ASTM F1980-07 <i>Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices</i>

- ISO 2233:2000 Packaging – complete, filled transport packages and unit loads – conditioning for testing
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.

The following is a list of all significant testing that was successfully completed:

Catheter and Insertion Tool

- Surface: external surface
- Radiodetectability of catheter/marker bands
- Dimensions: Catheter Markerband length
- Dimensions: Catheter Markerband placement
- Surface: Catheter PTFE Liner Inspection
- Dimensions: Catheter Tip Angle
- Dimensions: Catheter Tip Length
- Dimensions: Length, Diameter (ID/OD)
- Atraumatic Catheter Tip
- Markerband retention
- Torque Strength
- Kink resistance
- Buckling resistance
- Freedom from Liquid Leakage
- Freedom from Air Leakage
- Force at break(junction between catheter hub and tube)
- Force at break(junction between insertion tool hub and tube)
- Catheter hub with female luer
- Corrosion resistance

Safety & Performance Tests *continued*

System

- Snare Loop Resistance
- Guiding Catheter Resistance
- Snare insertion tool fitment
- Snare insertion
- Insertion Tool tear away force from the snare
- Snare inspection after insertion tool removal
- Snare loop protrusion

Biocompatibility testing included

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemolysis
- Thrombogenicity
- Complement Activation
- Chemical Tests

The subject Merit EN Snare Endovascular Snare System met the acceptance criteria applicable to the safety and effectiveness of the device. This has demonstrated the subject device Merit EN Snare Endovascular Snare System is substantially equivalent to the Primary Predicate Device#1 EN Snare Endovascular Snare System, K092343.

Merit Medical Systems, Inc.
Merit EN Snare Endovascular Snare System
Special Premarket Notification 510(k)

Section 5
510(k) Summary

**Summary of
Substantial
Equivalence**

Based on the Indications for Use, design, safety and performance testing, the subject Merit EN Snare Endovascular Snare System is substantially equivalent to the Primary Predicate Device#1 Merit EN Snare Endovascular Snare System, K092343 and the Reference Device#2, Merit ONE Snare System, 510(k), K122088 for Performance data.
