DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 4, 2017

Merit Medical Systems, Inc.
Niloufar Samimi
Regulatory Affairs Specialist II
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K172081
Trade/Device Name: Maestro Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: July 6, 2017
Received: July 10, 2017

Dear Niloufar Samimi:

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" (21 CFR 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K172081

Device Name
Maestro Microcatheter

Indications for Use *(Describe)*
The Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels. The catheter should not be used in the cerebral vessels.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

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| **General Provisions** | Submitter Name: Merit Medical Systems, Inc.<br>Address: 1600 West Merit Parkway<br>South Jordan, UT 84095<br>Telephone Number: (801) 208-4583<br>Contact Person: Niloufar Samimi<br>Date Prepared: 07/05/2017<br>Registration Number: 1721504 |
| **Subject Device** | Trade Name: Maestro Microcatheter<br>Common/Usual Name: Microcatheter<br>Classification Name: Continuous Flush Catheter<br>Regulatory Class: 2<br>Product Code: KRA<br>21 CFR §: 870.1210<br>Review Panel: Cardiovascular |
| **Predicate Device** | Trade Name: Maestro Microcatheter<br>Classification Name: Continuous Flush Catheter<br>Premarket Notification: K082613<br>Manufacturer: Merit Medical Systems, Inc.<br><br>This predicate has not been subject to a design-related recall |
| **Reference Device** | No reference devices were used in this submission. |
| **Device Description** | The Maestro Microcatheter is available in 2.8F (proximal) / 2.1F (distal) size and 110cm, 130cm and 150cm lengths. The distal tip of the microcatheter is offered in straight or pre-shaped 45 degree and swan neck configurations. The proximal end of the catheter consists of a molded winged hub with a tapered strain relief. The outer surface of the distal 80cm of the microcatheter shaft is coated with a hydrophilic coating designed to facilitate the introduction of the catheter into the vasculature. The microcatheter incorporates a radiopaque marker at the distal tip to facilitate fluoroscopic visualization.<br><br>The Maestro Microcatheter is offered with two 3ml syringes. |
| **Indications for Use** | There is no change in the Indications for Use Statement from the predicate to the subject device.<br><br>The Microcatheter is intended for general intravascular use, including peripheral and coronary vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels. The catheter should not be used in the cerebral vessels. |

The design and technological characteristics of the subject 2.8F/2.1F Maestro Microcatheter are substantially equivalent to those of the predicate Maestro Microcatheter. The subject device has the same basic design as the predicate device. The main difference between the subject and the predicate devices is in the French size to expand the product line to include the 2.8F/2.1F microcatheter. The comparison between the subject and the predicate devices is based on the following:

- Same intended use
- Same indications for use
- Similar material types that meet ISO 10993 biocompatibility requirements
- Same design
- Same sterilization methods
- Same fundamental technology/principle of operation

**Comparison to Predicate Device**

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject 2.8F/2.1F Maestro Microcatheter was conducted based on the risk analysis and based on the requirements of the following international standard:

- ISO 10555-1:2013, *Intravascular Catheters – Sterile and single-use catheters – Part 1: General requirements*
- ISO 11135:2014*, Sterilization of health care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices*
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*, May 1, 1995
- ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
- ISO 2233:2000, *Packaging – complete, filled transport packages and unit loads – conditioning for testing*
- ASTM D4169-14:2014, *Standard practice for performance testing of shipping containers and systems*

The following tests were performed to demonstrate there were no unacceptable risks associated with the changes made to the device:

Performance Testing-Bench

- Surface
- Tensile Force
- Dimensions
- Radio-detectability
- Freedom from Liquid Leakage
- Flow Rate
- Kink Resistance
- Lubricity
- Coating Coverage
- Delivery of Microspheres and Particles
- Torque Strength
- Particulate
- Tip Shape Retention
- Hub Migration from Clip

**Safety & Performance Tests cont.**

Design Validation

- Delivery of Coils
- Guidewire Compatibility
- Catheter Compatibility
- Torsion
- Negative Pressure Collapse
- Hoop Removal
- Distal Tip
- Tip Straightener
- Soft Distal Section
- Trackability
- Pushability
- Reposition of Guidewire

The results of the testing demonstrated that the subject 2.8F/2.1F Maestro Microcatheter met the predetermined acceptance criteria applicable to the safety and efficacy of the device. This has demonstrated the subject is substantially equivalent to the predicate device.

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| **Summary of Substantial Equivalence** | Based on the indications for use, design, safety and performance testing, the subject 2.8F/2.1F Maestro Microcatheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Maestro Microcatheter, K082613, manufactured by Merit Medical Systems, Inc.. |