March 30, 2023

Merit Medical System, Inc.
Garry Courtney
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K230636
Trade/Device Name: Maestro Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: February 6, 2023
Received: March 7, 2023

Dear Garry Courtney:

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2023.03.30 15:22:51 -04'00'

Lydia Glaw
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)*
K230636

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.

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510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Contact Person: Date Prepared: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4583 Garry A. Courtney 03/03/2023 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	Maestro Microcatheter Microcatheter Continuous Flush Catheter 2 KRA 870.1210 Cardiovascular
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer: This predicate has not been subject to a design-related recall	Maestro Microcatheter Continuous Flush Catheter K172081 Merit Medical Systems, Inc.
Reference Device	Merit Medical Maestro Microcatheter – K082613	

Device Description	The Maestro Microcatheter is available in working length sizes 110cm, 130cm, 150cm, 165cm and 175cm 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. 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. 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.

Comparison to Predicate Device	The design and technological characteristics of the subject "longer length" Maestro Microcatheters 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 working length of the microcatheter – where longer length catheters (165cm and 175cm) are made available to address clinical needs. 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 No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Maestro Microcatheters 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 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

Safety & Performance Tests cont.	The following tests were performed to demonstrate there were no unacceptable risks associated with the changes made to the device: <u>Performance Testing-Bench</u> • Effective Length Analysis • Soft Flexible Transition Length • Proximal Shaft OD • Proximal Hub ID • Coating Length • Freedom from Liquid Leakage (Pressure Test) • Freedom from Air Leakage • Peak Tensile Force • Torque Strength <u>Design Validation</u> • Hoop Removal • Soft Distal Section • Distal Tip • Straightener • Guidewire Compatibility • Pushability • Catheter Compatibility • Trackability • Torsion • Reposition Guidewire • Negative Pressure • Delivery of Coil The results of the testing demonstrated that the subject “longer length” Maestro Microcatheters met the predetermined acceptance criteria applicable to the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject “longer length” Maestro Microcatheters meet the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Maestro Microcatheter, K172081, manufactured by Merit Medical Systems, Inc..