March 30, 2018

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

Re: K173548
Trade/Device Name: Merit Pursue Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 5, 2018
Received: November 17, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173548

Device Name
Merit Pursue 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 diagnostics, 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."

K173548- 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 Niloufar Samimi 11/15/2017 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name: Regulatory Class: Product Code: 21 CFR §: Review Panel:	Merit Pursue Microcatheter Microcatheter Percutaneous catheter 2 DQY 870.1250 Cardiovascular
Predicate Device	**Premarket Notification Predicate #1:** Trade Name: Classification Name: Premarket Notification: Manufacturer: **Premarket Notification Reference Predicate #2:** Trade Name: Classification Name: Premarket Notification: Manufacturer: These predicate devices have not been subject to a design-related recall.	 Excelsior™ 1018™ and SL-10 Pre-Shaped Microcatheter Percutaneous catheter K042568 Stryker Maestro Microcatheter Catheter, Continuous Flush K172081 Merit Medical System, Inc.
Device Description	The Merit Pursue Microcatheter is available in two French configurations,2.9F (proximal) / 2.0F (distal) and 2.8F (proximal / 1.7F (distal) 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 microcatheter 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 microcatheter into the vasculature. The microcatheter incorporates a radiopaque marker at the distal tip to facilitate fluoroscopic visualization. The Merit Pursue Microcatheter is offered with two 3mL syringes.
Indications for Use	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 Devices	The design and technological characteristics of the subject Merit Pursue Microcatheter are substantially equivalent to those of the Predicate Device #1, Excelsior™ 1018™ and SL10- Pre-shaped Microcatheter and Reference Predicate Device #2 Maestro Microcatheter. The subject device has a similar basic design as the predicates. The comparison between the subject and the predicate devices is based on the following: • Similar Intended use • Similar Indications for use • Similar material types that meet ISO 10993 biocompatibility requirements • Similar design • Same sterilization methods • Same fundamental technology/principle of operation
Performance Data	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 Pursue Microcatheter was conducted based on the risk analysis and based on the requirements of the following international standards: • 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/Technical Corrigendum 1 2010 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing

within a risk management process, and FDA guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (2010)*

- ISO 10993-4: 2017, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood
- ISO 10993-4:2002/Amendment 1 2006*, Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood*
- ISO 10993-5:2009, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2006, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- United States Pharmacopeia 40, National Formulary 35, 2017 <151> Pyrogen Test
- ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials
- 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*
- *ISO 594-2: 1998 Conical fittings with 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 2: Lock fittings*

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Merit Pursue Microcatheter was conducted in accordance with FDA guidance use of International standard ISO-10993, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The battery of testing included the following tests:

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

The Merit Pursue Microcatheter is considered to have circulating blood contact for a limited (< 24 hours) duration.

Performance Data cont.	Performance Testing-Bench ISO 594-2 Performance testing/ Design verification • Gauging • Separation Force • Unscrewing Torque • Ease of Assembly • Resistance to Overriding • Stress Cracking ISO 10555-1 Performance testing • Surface • Freedom from Liquid Leakage • Freedom from Air Leakage • Power injection • Peak Tensile Force • Corrosion Resistance Additional Testing (Design verification and validation) • Lubricity • Dimensional testing • Design Validation • Marker Band Retention • Tip Shape • Torque Strength • Radio-detectability • Kink Resistance • Chemical Compatibility • Particulate Analysis
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Merit Pursue Microcatheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the Predicate Device #1 Stryker, the Excelsior 1018 and SL-10 [K042568].