November 26, 2019

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

Re: K192907
Trade/Device Name: Advocate PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: October 10, 2019
Received: October 15, 2019

Dear Mr. 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,

For

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)*
K192907

Device Name
Advocate PTA Catheter

Indications for Use *(Describe)*
The Advocate PTA Catheter is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.

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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Merit Medical Systems, Inc.
Merit Advocate PTA Catheter
Traditional Premarket Notification 510(k)

Section 5
510(k) Summary

General Provisions

Submitter Name: Merit Medical Systems, Inc.
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Registration Number: 1721504

Correspondent Name: Merit Medical Ireland Ltd.
Address: Parkmore Business Park
Parkmore, Galway, Ireland
Telephone Number: (+353) 91 703700 (Ext. 3223)
Fax Number: (+353) 91 680104
Contact Person: Michael O'Sullivan
Date of Preparation: 3 October 2019
Registration Number: 9616662
510(k) Number: K192907

Subject Device

Trade Name: Advocate PTA Catheter
Common/Usual Name: Percutaneous Catheter
Classification Name: Catheter, Angioplasty, Peripheral, Transluminal

Predicate Device

Premarket Notification Predicate:
Trade Name: Advocate PTA Catheter
Classification Name: 21 CFR 870.1250 Percutaneous Catheter
Premarket Notification: K173621
Manufacturer: Merit Medical

Premarket Notification Reference Predicate:
Trade Name: Pirouette 018HP
Classification Name: 21 CFR 870.1250 Percutaneous Catheter
Premarket Notification: K172033
Manufacturer: Arravasc

Merit Medical Systems, Inc.
Merit Advocate PTA Catheter
Traditional Premarket Notification 510(k)

Classification	Class II 21 CFR § 870.1250 Product code: LIT Division of Cardiovascular Devices
Indications for use	The Advocate PTA Catheter is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
Intended Use	The Advocate PTA catheter is intended for use to treat vascular stenoses, abnormal narrowing of a blood vessels, in various clinical settings during endovascular procedures for adult patient populations
Device Description	The Advocate PTA Catheter consists of two lumens, a compatible guidewire lumen (0.014", 0.018" or 0.035") extending from guide wire port in the manifold to the catheter distal tip, and an inflation lumen extending from the proximal inflation port in the manifold to the balloon interior. There are various size balloons in the product matrix, ranging from 2.0-12.0mm in diameter and 15-300mm in length. The catheter has two radiopaque marker bands that facilitate visibility and location during the placement and inflation of the balloon. The catheter is inserted through a 4Fr, 5Fr, 6Fr or 7Fr haemostatic or non haemostatic introducer, depending on the model selected.

Merit Medical Systems, Inc.
Merit Advocate PTA Catheter
Traditional Premarket Notification 510(k)

Comparison to Predicate

There are no technological differences between the subject and predicate devices. The changes to the device for this submission are as follows

- Indications for Use Change to: The Advocate PTA Catheter is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal, renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae.
- Removal of the 1.25mm and 1.5mm Balloon diameters from the list of applied 0.014 devices
- Change of Manufacturing location from Subcontractor at Arravasc in Galway to Merit Medical in Galway, using the same processes as already qualified for the device.

The only difference between the two devices are the indications for use, the Manufacturing location and the removal of Devices with balloon diameters of 1.25mm and 1.5mm.

Safety & Performance Tests

The existing Safety or Performance testing was not performed for the manufacturing location move as the process used is the same as already qualified by Arravasc Ltd when they acted as a subcontractor manufacturing location for the device. The processes were transferred into Merit Galway as is and were used to manufacture the devices that make up this submission. The process is the same as previously qualified under K173621.

However, extra Validation testing was done on the device to qualify the expanded indications for use, that this change is introducing.

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

- Deliverability – AVF Trackability
- Deliverability – Pushability

Merit Medical Systems, Inc.
Merit Advocate PTA Catheter
Traditional Premarket Notification 510(k)

Summary of Substantial Equivalence	Based on the comparisons noted, the subject Merit Advocate PTA Catheter meets the requirements that are considered essential for its intended use and is substantively equivalent to the Predicate Device, the Advocate PTA Catheter [K173621] manufactured by Merit Medical.