December 13, 2017

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

Re: K173621
Trade/Device Name: Advocate PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: LIT
Dated: November 20, 2017
Received: November 22, 2017

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. 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 Kenneth J. Cavanaugh -S

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)*
K173621

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, and renal arteries.

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.

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510(k) Summary

General Provisions

Submitter Name:	Merit Medical Systems, Inc.
Address:	1600 West Merit Parkway South Jordan, UT 84095
Telephone Number:	(+353) 91 703700 (Ext. 3061)
Fax Number:	(+353) 91 680104
Contact Person:	Mark Mullaney
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:	20 November 2017
Registration Number:	9616662

Subject Device

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

Predicate Device	**Premarket Notification Predicate #1:** Trade Name: Pirouette 014 Classification Name: 21 CFR 870.1250 Percutaneous Catheter Premarket Notification: K162316 Manufacturer: Arravasc Limited **Premarket Notification Predicate #2:** Trade Name: Pirouette 018 Classification Name: 21 CFR 870.1250 Percutaneous Catheter Premarket Notification: K151153 Manufacturer: Arravasc Limited **Premarket Notification Predicate #3:** Trade Name: Pirouette 035 Classification Name: 21 CFR 870.1250 Percutaneous Catheter Premarket Notification: K161427 Manufacturer: Arravasc Limited
Classification	Class II 21 CFR § 870.1250 Product code: LIT Division of Cardiovascular Devices
Intended Use	The Advocate PTA Catheter is intended for balloon dilation of the iliac, femoral, popliteal, infra-popliteal, and renal arteries.
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 20-300mm 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.

Comparison to Predicate	There are no technological differences between the subject and predicate devices. They device is manufactured under contract by the same Manufacturer who makes the identical device under the Pirouette name. The only difference between the two devices in in the naming and labelling of the product, with the Merit product named and labelled as the “Advocate PTA Catheter”.
Safety & Performance Tests	No Safety or Performance testing is required to establish the safety and efficacy of the subject device
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 three Predicate Devices, the Pirouette 014, 018 and 035 [K162316, K151153, K161427], manufactured by Arravasc Limited.