Merit Medical Systems, Inc.
Michael O'sullivan
Senior Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Galway H91 W274, Ireland

Re: K201595
Trade/Device Name: Merit Hydrophilic Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 9, 2020
Received: June 12, 2020

Dear Michael 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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201595

Device Name
Merit Hydrophilic Guidewire

Indications for Use *(Describe)*
Intended to be used in the peripheral vascular system to facilitate the placement of devices during diagnostic and interventional procedures.

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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Department of Health and Human Services
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Office of Chief Information Officer
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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."

K201595
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:	09 June 2020
	Registration Number:	9616662
Subject Device	Trade Name:	Merit Hydrophilic Guide Wire
	Common/Usual Name:	Guide Wire
	Classification Name:	Wire, Guide, Catheter
Predicate Device	**Premarket Notification Predicate:**	
	Trade Name:	Merit Hydrophilic Guide Wire
	Classification Name:	21 CFR 870.1330 Catheter Guide Wire
	Premarket Notification:	K170933
	Manufacturer:	Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.1330 Product code: DQX Division of Cardiovascular Devices	

Intended Use	The Merit Hydrophilic Guide Wire is intended to be used in the peripheral vascular system to facilitate the placement of devices during diagnostic and interventional procedures.
Device Description	The Merit Hydrophilic Guide Wire consists of a jacketed core wire with a hydrophilic coating applied to the jacket. The wire will be offered in straight and angled tip shapes, standard and stiff wire configurations, and in various wire lengths and wire diameters.
Comparison to Predicate	Technological characteristics of the subject Merit Hydrophilic Guide Wire are substantially equivalent to those of the predicate Merit Hydrophilic Guide Wire [K170933]. The Nitinol core and polyurethane plastic jacket of the subject Merit Hydrophilic Guide Wire remain unchanged from the predicate Merit Hydrophilic Guide Wire [K170933]. The pre-coating step on the predicate has been replaced by a new base-coating of polyurethane on the subject device, which is applied to the polyurethane plastic jacket. While the predicate has two coating applications of the hydrophilic polymer, the subject device has a single application of the same polymer. The coating material formulation has been modified, and there are also some changes in material quantities for the post-coating step. Process parameters such as oven timings and temperatures have been modified also.
Safety & Performance Tests	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. A battery of testing was conducted, on the subject Merit Hydrophilic Guide Wire, in accordance with protocols based on requirements outlined in guidance's and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence. Where appropriate, the tests were based on the requirements of the following documents:

1. FDA Guidance “Coronary, Peripheral, and Neurovascular Guidewires -Performance Tests and Recommended Labelling- Guidance for Industry and Food and Drug Administration Staff” – October 2019
2. FDA Guidance – “Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations” – October 2019
3. ISO 11070:2014, Sterile Single-Use Intravascular Catheter Introducers.
4. 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.
5. ASTM F1980-07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
6. ISO 10993-1:2018, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process, and the FDA Guidance for Industry, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

The subject Merit Hydrophilic Guide Wire was compared to the predicate device for various performance attributes that support substantial equivalence of the device.

The following testing was successfully completed:

<u>Performance Testing</u>

1. Size Designation
2. Surface
3. Torqueability
4. Fracture Test
5. Flex Test
6. Lubricity/Coating Integrity
7. Clinical Acceptability
8. Particulate Testing
9. Needle Compatibility – Design Validation
10. Lubricity/Coating Integrity - Design Validation
11. Clinical Assessment - Design Validation
12. Catheter Compatibility - Design Validation

<u>Biocompatibility</u>

	• Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Hemocompatibility - Hemolysis • Hemocompatibility - Thrombogenicity • Hemocompatibility - Complement Activation All test results were comparable to the predicate devices and the subject Merit Hydrophilic Guide Wire met the predeterminded acceptance criteria.This has demonstrated that the subject device is substantially equivalent to the predicate device.
Summary of Substantial Equivalence	Based on the Indications for Use, design, safety and performance testing, the subject Merit Medical Hydrophilic Guide Wire meets the requirements that are considered essential for its intended use and is substantially equivalent to the Merit Hydrophilic Guide Wire [K170933] predicate device.