



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 16, 2014

Merit Medical Systems, Inc.
Mr. Michael O'Sullivan
RA Specialist III
Parkmore Business Park West
Galway, Ireland

Re: K141295
Trade/Device Name: Merit Hydrophilic Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 20, 2014
Received: October 23, 2014

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kenneth J. Cavanaugh -S

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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K141295

Device Name

Merit Hydrophilic Guide Wire

Indications for Use (Describe)

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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.”

Section 5 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
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	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:	15 th May 2014
	Registration Number:	9616662

Subject Device	Trade Name:	Merit Hydrophilic Guide Wire
	Common/Usual Name:	Hydrophilic Guide Wire
	Classification Name:	Catheter Guide Wire

Predicate Device	Premarket Notification Predicate Device # 1:
	Merit Hydrophilic Guide Wire K131710
	Manufacturer: Merit Medical Systems, Inc
	Premarket Notification Predicate Device # 2:
	Merit Hydrophilic Guide Wire K130588
	Manufacturer: Merit Medical Systems, Inc
	Premarket Notification Predicate Device # 3:
	Merit Hydrophilic Guide Wire K123609
	Manufacturer: Merit Medical Systems, Inc
	Premarket Notification Predicate Device # 4:
	Merit Hydrophilic Guide Wire K120644
	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.
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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, angled, standard and stiff configurations, in various lengths.
Comparison to Predicate	Technological characteristics of the subject Merit Hydrophilic Guide Wire are substantially equivalent to those of the predicates, the Merit Hydrophilic Guide Wires [K131710], [K130588], [K123609] and [K120644]. The difference between the devices relate to the process of application of the hydrophilic coating and the modification of the volume quantities of some materials. The guide wire design and indications remain unchanged.
Safety & Performance Tests	<p>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 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.</p> <p>Where appropriate, the tests were based on the requirements of the following documents:</p> <ul style="list-style-type: none">• FDA guidance Coronary and Cerebrovascular Guide Wire Guidance January 1995.• ISO 11070: 1998, <i>Sterile Single-Use Intravascular Catheter Introducers</i>.• ISO 11135-1: 2007 <i>Sterilization of health care products-Ethylene oxide-Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices</i>.• ASTM F1980-07 <i>Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices</i>• ISO 10993-1: 2009, <i>Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process</i>, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1. <p>The Merit Hydrophilic Guide Wire was compared to the predicate device(s) for various performance attributes that support substantial equivalence of the device. Performance testing was performed on the 0.018" and 0.038" diameter wires only, as these represent the minimum and maximum wire diameters within the cleared device range and Merit believes that the testing on these (min/max) diameters is sufficient to demonstrate equivalence for the intermediate diameter wires of 0.025" and 0.035" also.</p> <p>The following is a list of all significant testing that was successfully completed:</p> <p>Coating Adherence/Integrity(Including Anatomical Model), Catheter Compatibility (Durability), Surface, Fracture test, Flex test, Size Designation/ Dimensions, Particulate Evaluation and Biocompatibility testing.</p> <p>As all test results were comparable to the predicate devices and as the subject Merit Hydrophilic guide wire met the predetermined acceptance criteria applicable to the safety and efficacy of the device, this has demonstrated the subject device is substantially equivalent to the predicate devices.</p>

**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 substantively equivalent to the predicate devices, the Merit Hydrophilic Guide Wires manufactured by Merit Medical Systems Inc., K131710(0.018”), K130588(0.025”), K123609(0.038”) and K120644(0.035”).
