MERIT MEDICAL®

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K120644

SEP 19 2012

Section 5

510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway, South Jordan, UT 84095 (801) 208-4349 (801) 253-6967 Stephanie Erskine 1721504
	Correspondent Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Ireland Ltd. Parkmore Business Park, Galway, Ireland (353) 91 703 761 (353) 91 771 888 Mark Mullaney March 1, 2012 9616662
Subject Device	Trade Name: Common/Usual Name: Classification Name:	Merit Hydrophilic Guide Wire Hydrophilic Guide Wire Catheter Guide Wire
Predicate Devices	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Merit Hydrophilic Guide Wire Catheter Guide Wire K092303 Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.1330, 74 DQX Division of Cardiovascular Devices	
Intended Use	The Merit Hydrophilic Guide Wire is intended 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 with straight and angled tip configurations in various lengths.	

Comparison to Predicate	Technological characteristics of the subject Merit Hydrophilic Guide Wire are substantially equivalent to those of the predicate, the Merit Hydrophilic Guide Wire [K092303]. The differences between the devices relate to the hydrophilic coating process. The guide wire design remains unchanged.

Safety & Performance Tests

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, a battery of tests was performed according to protocols based on the requirements of industry standards and guidances and were shown to meet the acceptance criteria that were determined to demonstrate the safety and efficacy of the device.

Where appropriate, the tests were based on the requirements of the following documents:

- FDA Guidance *Coronary and Cerebrovascular Guide Wire Guidance* January 1995.
- ISO 11070:1998, *Sterile Single-Use Intravascular Catheter Introducers.*
- ISO 11135-1:2007, *Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.*
- ASTM F756-08 *Standard Practice for Assessment of Hemolytic Properties of Materials*
- ASTM F1980-07 *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*
- ISO 10993-1:2009, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and the FDA Modified ISO 10993 Test Profile FDA Memo G95-1.
- ISO 10993-5:2009 – *Biological Evaluation of Medical Devices – Part 5: Tests for In-Vitro Cytotoxicity*
- ISO 10993-7:2008 - *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*
- ISO 10993-18:2005 – *Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials*

The Merit Hydrophilic Guide Wire was compared to the predicate device for various performance attributes that demonstrate the safety or efficacy of the device. Differences in materials between the modified device and the cleared device [K092303] raised no issues of safety and effectiveness. The hydrophilic coating process was modified. The coating solution is made with the identical raw materials, equipment, and processes used for the preparation of the predicate coating solution.

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

- Coating Adherence/Integrity
- Catheter Compatibility
- Surface
- Fracture Test
- Flex Test
- Size Designation
- Biocompatibility
- Chemical Characterization

Summary of Substantial Equivalence	Based on the indications for use, design, safety, and performance testing, the subject Merit Hydrophilic Guide Wire meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Merit Hydrophilic Guide Wire manufactured by Merit Medical Systems, Inc. Differences between the two devices do not raise any significant issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 19 2012

Merit Medical Systems, Inc.
Mr. Mark Mullaney
Regulatory Affairs Manager
Parkmore Business Park West,
Galway, Ireland

Re: K120644
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: September 10, 2012
Received: September 12, 2012

Dear Mr. Mullaney:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4

Indications for Use Statement

510(k) Number (if known): K120644

Device Name: Merit Hydrophilic Guide Wire

Indications for Use:

The Merit Hydrophilic Guide Wire is intended to facilitate the placement of devices during diagnostic and interventional procedures.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120644