Section 6

510(k) Summary

General Provisions

Submitter Name:	Merit Medical Systems, Inc.
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Telephone Number:	(+353) 91 703700 (3061)
Fax Number:	(+353) 91 680 104
Contact Person:	Mark Mullaney
Registration Number:	9616662

JUL 29 2013

Correspondent Name:	Merit Medical Ireland Ltd.
Address:	Parkmore Business Park Parkmore, Galway, Ireland
Telephone Number:	(+353) 91 703700 (3168)
Fax Number:	(+353) 91 680 104
Contact Person:	Martha Folan
Date of Preparation:	26th June 2013
Registration Number:	9616662

Subject Device

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

Predicate Device

Trade Name: Merit Hydrophilic Guide Wire
Classification Name: Catheter Guide Wire

Premarket Notification Predicate Device # 1:
Merit Hydrophilic Guide Wire K120644
Manufacturer: Merit Medical Systems, Inc

Premarket Notification Predicate Device # 2:
Radiofocus® Glidewire® K863138
Manufacturer: Terumo Medical Corp.

Premarket Notification Predicate Device # 3
Merit Hydrophilic Guide Wire K130588
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 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 [K120644]. The difference between the devices relates to the guide wire diameter size. The guide wire design remains unchanged. Predicate device #2 [K863138] Terumo Radiofocus® Glidewire® is the predicate for performance testing parameters. Predicate device #3 [K130588] includes clarification of the Intended use statement.

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 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:

- 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 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.

The Merit Hydrophilic Guide Wire was compared to the predicate device(s) for various performance attributes that support substantial equivalence of the device. The difference in wire diameter between the modified device and the cleared device [K120644] has raised no new issues. Performance testing was based on Predicate device # 2 [K863138] Terumo Radiofocus® Glidewire®.

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

Tensile Strength, Torque Strength, Torquability, Tip Flexibility, Coating Adherence/Integrity (including Evaluation using Anatomical Model), Catheter Compatibility (Durability), Surface, Fracture Test, Flex test, Size Designation/ Dimensions and Radiopacity.
As all test results were comparable to the predicate devices and the subject Merit Hydrophilic guide wire met the predeterminded acceptance criteria applicable to the safety and efficacy of the device,this has demonstrated the subject device is substantially equivalent to predicate devices.

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 device, the Merit Hydrophilic Guide Wire manufactured by Merit Medical Systems Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 29, 2013

Merit Medical Systems, Inc.
Ms. Martha Folan
Senior Regulatory Affairs Specialist
Parkmore Business Park West
Galway, Ireland

Re: K131710
Trade/Device Name: Merit Hydrophilic Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guide wire
Regulatory Class: II
Product Code: DQX
Dated: June 27, 2013
Received: July 1, 2013

Dear Ms. Martha Folan:

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 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. 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,

Bram D. Zuckerman -S

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

Section 5

Indications for Use Statement

510 (k) Number:

Device Name: Merit Hydrophilic Guide Wire

Indications for 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.

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)

Bram D. Zuckerman -S
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