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

April 6, 2017

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

Re: K170700
Trade/Device Name: InQwire Amplatz Super Stiff Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 6, 2017
Received: March 7, 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.

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,

Fernando Aguel -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

Indications for Use

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

510(k) Number *(if known)*
K170700

Device Name
InQwire Amplatz Super Stiff Guide Wire

Indications for Use *(Describe)*
Merit Medical guide wires are used 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.

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Section 5
510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
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	Registration Number:	1721504
	Correspondent Name:	Merit Medical Ireland Ltd.
	Address:	Parkmore Business Park West Galway, Ireland
	Telephone Number:	(+353) 91 703700 (3223)
	Fax Number:	(+353) 91 680 104
	Contact Person:	Michael O'Sullivan
	Date of Preparation:	5/Apr//2017
	Registration Number:	9616662
Subject Device	Trade Name:	InQwire® Amplatz
	Common/Usual Name:	Merit Medical Guide Wire
	Classification Name:	21 CFR 870.1330 Catheter guide wire
Predicate Device	**Premarket Notification Predicate #1: (Primary Predicate)**	
	Trade Name:	InQwire®
	Classification Name:	21 CFR 870.1330 Catheter guide wire
	Premarket Notification:	K163575
	Manufacturer:	Merit Medical Systems, Inc.
	Premarket Notification Reference Device	
	Trade Name:	Amplatz Super Stiff Guidewire
	Classification Name:	21 CFR 870.1330 Catheter guide wire
	Premarket Notification:	K843012
	Manufacturer:	Boston Scientific Corporation
Classification	Class II 21 CFR 870.1330 Catheter guide wire FDA Product Code: DQX Review Panel: Division of Cardiovascular Devices	
Intended Use	Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.	
Device Description	Merit InQwire® Amplatz Super Stiff Guide Wires are intended to facilitate the placement of devices during diagnostic and interventional procedures. The guide wires consist of a Blue PTFE (Polytetrafluoroethylene) coated flat wire coil, with an inside core wire. The core wire enhances the "Super Stiff" characteristic of the guide wire. The core wire extends the full length of the coil and is welded to the coil at three (3) points; a) the distal end, b) the proximal end and c) a spot weld approx. 22cm from the distal end. These welds are designed to provide integrity and ensure that the guide wire components remain together The outside coil is PTFE coated	

	and this Blue PTFE coating extends from the distal tip of the wire to within 7cm of the proximal tip, which remains uncoated. The Merit InQwire® Amplatz Super Stiff Guide Wires are offered in 0.035-inch and 0.038-inch outer diameter with a 1cm, 3cm, 3.5cm ,4cm, 6cm and 7cm straight and J tip configuration and are available in lengths from 75cm to 260cm. The wires will be provided in a spiral hoop dispenser sized appropriately for the wires diameter and length. The dispenser has a standard flush port luer adapter that accepts any standard luer lock or slip tip syringe to facilitate flushing of the guide wire prior to use. A J-straightener is provided on the dispenser to facilitate the advancement of the wire tip into other devices.
Comparison to Predicate	The changes to the device are as follows; a) A new variant of the core wire OD (0.38") has been added to the range, b) 5 new Tip lengths have been added (1cm, 3cm, 3.5cm, 4cm and 6cm), spread across the two ODs and c) A J Tip shape variant is also added to the range, spread across the two ODs. None of the above changes would be deemed sufficient to affect the technological characteristics of the device and thus the subject Merit InQwire® Amplatz Super Stiff Guide Wire is substantially equivalent to Predicate Device #1, the Merit InQwire® Amplatz Super Stiff Guide Wire [K163575 and the Reference Device, the Amplatz Super Stiff Guidewire [K843012].]. The proposed new wires add in a new OD of 0.038" as well as Tip length (1cm, 3cm, 3.5cm, 4cm and 6cm) and Tip shape (J tip) variants to the range. The lengths, of 75cm to 260cm, are within the bracketed range of the predicate (75cm to 260cm). The Indications for use of the subject wire are identical to Predicate Device #1.
Safety & Performance Tests	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Merit InQwire® Amplatz Super Stiff Guide Wire was conducted based on risk analysis. 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 11070:2014, *Sterile Single-Use Intravascular Catheter Introducers.* • ISO 11135:2014 *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. • ISO 11607-1:2006, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems The Merit InQwire® Amplatz Super Stiff Guide Wire was compared to the predicate device for various performance attributes that support substantial equivalence of the device. The difference in assembly between the modified device and the cleared device, Merit InQwire® Amplatz Super Stiff Guide Wire [K163575] has raised no new issues. In some instances, performance characteristic testing was based on the Reference Device, the Amplatz Super

Stiff Guidewire [K843012], when it was deemed to be relevant.

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

Size Designation	Radiopacity	Tensile Strength	Torque Strength
Tip Flexibility	Coating Adherence/Integrity • Fracture • Flex • Particulate Evaluation	Catheter and Needle Compatibility	Lubricity
Surface	Biocompatibility	Corrosion	Tip Shape

All test results were comparable to the predicate devices and the subject Merit InQwire® Amplatz Super Stiff Guide Wire met the predeterminded acceptance criteria. This has demonstrated that the subject device is substantially equivalent to the predicate devices.

Summary of Substantial Equivalence

Based on the Indications for Use, design, safety and performance testing, the subject Merit InQwire® Amplatz Super Stiff Guide Wire is substantially equivalent to the predicate devices, the cleared Predicate Device #1, the Merit InQwire® Amplatz Super Stiff Guide Wire [K163575] and the Reference Device, the Amplatz Super Stiff Guidewire [K843012].