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 21, 2017

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

Re: K170532
Trade/Device Name: True Form Reshapable Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: June 15, 2017
Received: June 19, 2017

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. 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,

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

Indications for Use

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

510(k) Number *(if known)*

K170532

Device Name
True Form Reshapable Guide Wire

Indications for Use *(Describe)*

The True Form Reshapable Guide Wire is intended to facilitate the placement of catheters within the peripheral and coronary vasculature for various diagnostic and interventional procedures.

The True Form Reshapable Guide Wire should not be used in the neurovasculature

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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K170532
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: 20th February 2017 Registration Number: 9616662
Subject Device	Trade Name: True Form Reshapable Guide Wire Common/Usual Name: Guide Wire Classification Name: Wire, Guide, Catheter
Predicate Device	**Premarket Notification Predicate #1:** Trade Name: Boston ChoICE PT Classification Name: 21 CFR 870.1330 Catheter guide wire Premarket Notification: K143587 Manufacturer: Boston Scientific Corporation **Premarket Notification Reference Predicate #2:** Trade Name: Bard Porter Classification Name: 21 CFR 870.1330 Catheter guide wire Premarket Notification: K060551 Manufacturer: Brivant Ltd.
Classification	Class II 21 CFR § 870.1330 Product code: DQX Division of Cardiovascular Devices

Intended Use	The True Form Reshapable Guide Wire is intended to facilitate the placement of catheters within the peripheral and coronary vasculature for various diagnostic and interventional procedures. The True Form Reshapable Guide Wire should not be used in the neurovasculature
Device Description	The Merit True Form Reshapable Guide Wire consists of a stainless steel core wire, flattened at the distal end, with a 5cm Gold Plated Tungsten coil attached to the distal tip and is fully jacketed with a radiopaque filled polymer jacket. The True Form Reshapable Guide Wire is fully coated with a hydrophilic coating. The 5cm radiopaque coil is attached to the internal stainless steel core wire with a multitude of solder joints. The wires are placed within a spiralled hoop dispenser with a flush luer attached and clips to secure the wire within the hoop. Included within the pouch, with the spiralled hooped guidewire, is another pouch containing an Insertion Tool, a Tip Straightener, and a Torque device. The wire will be offered in straight and angled versions, in various lengths.
Comparison to Predicate	The Technological characteristics of the subject Merit True Form Reshapable Guide Wire are substantially equivalent to those of Predicate Device #1, the Boston Choice PT[K143587] and Reference Predicate #2, the Bard Porter [K060551]. The subject device has the same basic design as the predicates, in that they all consist of a metallic core wire covered in a radiopaque polymer jacket with some or all the wire jacket having a hydrophilic coating. The fundamental technology and operating principles of the subject and the predicates are the same and while the indications for use wordings are not identical, the intended use is the same, with all wires used for the placement of devices during intravascular procedures.
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 Merit True Form Reshapable 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:

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

<u>Performance Testing-Bench</u>

- Size Designation
- Radiodetectability
- Tip Shape Testing
- Surface
- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Fracture test
- Flex test
- Lubricity
- Corrosion Resistance
- Device Compatibility
- Tip Curve Shapeability
- Particulate
- Coating Durability
- Packaging

	Biocompatibility • Cytotoxicity • Sensitization • Irritation • Acute Systemic Toxicity • Pyrogenicity • Genotoxicity • Hemolysis • Thrombogenicity • Complement Activation All test results were comparable to the predicate devices and the subject Merit True Form Reshapable 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 True Form Reshapable Guide Wire meets the requirements that are considered essential for its intended use and is substantively equivalent to Predicate Device #1, the Boston Choice PT [K143587]. manufactured by Boston Scientific Corporation and Reference Predicate #2, the Bard Porter [K060551], manufactured by Brivant Ltd.