April 8, 2020

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

Re: K193571
Trade/Device Name: Go2Wire Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 5, 2020
Received: March 9, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193571

Device Name

Go2Wire Guide Wire

Indications for Use *(Describe)*

The Merit GO2WIRE™ is intended to facilitate the placement and exchange of devices during peripheral diagnostic and interventional procedures.

Carefully read all instructions prior to use. Observe all warnings and cautions noted throughout these instructions. Failure to do so may result in complications.

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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Merit Medical Systems, Inc.
Merit Go2Wire Guide Wire
Traditional Premarket Notification 510(k)

Section 5
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: 20 December 2019 Registration Number: 9616662
Subject Device	Trade Name: Go2Wire Guide Wire Common/Usual Name: Guide Wire Classification Name: Wire, Guide, Catheter
Predicate Device	**Premarket Notification Predicate:** Trade Name: Wholey Guide Wire System Classification Name: 21 CFR 870.1330 Catheter Guide Wire Premarket Notification: K120863 Manufacturer: Covidien LLC.
Classification	Class II 21 CFR § 870.1330 Product code: DQX Division of Cardiovascular Devices
Intended Use	The Merit GO2WIRE™ is intended to facilitate the placement and exchange of devices during peripheral diagnostic and interventional procedures. Carefully read all instructions prior to use. Observe all warnings and cautions noted throughout these instructions. Failure to do so may result in complications.

Device Description	The Merit Go2Wire guide wire will consist of 0.035" guide wire configurations available in 145, 175, 210, 260, and 300cm. The distal tip flex configurations are Floppy, Standard and Intermediate (Modified J). The distal tip shapes are either straight or modified J. The wire is composed of a stainless-steel core wire, a PTFE coated coil, a white PTFE sleeve, a platinum-tungsten marker coil, and an optional extension system connector. The wire's proximal end is covered by a white PTFE sleeve that terminates at 100cm from the distal tip. The distal 100 cm of the wire is covered with a green PTFE pre-coated coil. The PTFE coated coil and platinum-tungsten coil are welded to the core on the very distal tip. The distal tip is shapeable and radiopaque. A torque device is included to facilitate wire steering within the vascular anatomy. An 0.035" extension wire consisting of PTFE coated stainless steel 155cm in length to extend the length of the wire to allow initial usage with a short wire and then extendable to allow catheter exchanges when required.
Comparison to Predicate	The Technological characteristics of the subject Merit Go2Wire Guide Wire are substantially equivalent to those of Predicate Device, the Wholey Guide Wire System[K120863]. The Wholey Guide wire was fully characterized by Merit and an equivalent wire was developed by Merit based upon this characterization. The subject device has the same basic design as the predicate, in that they are composed of a stainless-steel core wire, a PTFE coated coil, a white PTFE sleeve, a platinum-tungsten marker coil, and an optional extension system connector. 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 and exchange of devices during peripheral diagnostic and interventional 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 Go2Wire 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, Peripheral, and Neurovascular Guidewires -Performance Tests and Recommended Labelling- Guidance for Industry and Food and Drug Administration Staff" – October 2019
- FDA Guidance – "Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations" – October 2019
- 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 10993-1:2018, 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
- Surface
- Tensile Strength
- Torque Strength
- Torqueability
- Tip Flexibility
- Fracture test
- Flex test
- Torturous Path Lubricity
- Corrosion Resistance
- Tip Shape Testing - Validation
- Catheter and Needle Compatibility – Validation
- Guidewire Clinical Use in Model – Validation

- Extension System Clinical Use in Model - Validation
- Particulate

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 Go2Wire 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 comparisons noted, the subject Merit Go2Wire Guide Wire meets the requirements that are considered essential for its intended use and is substantively equivalent to the Predicate Device, the Wholey Guide Wire System [K120863] manufactured by Covidien LLC