October 28, 2023

Merit Medical Systems, Inc.
℅ James Kenny
Senior Regulatory Affairs Specialist
Merit Medical Ireland, Ltd.
Parkmore Business Park West
Galway, Ireland

Re: K230418
Trade/Device Name: Mighty Wire Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 29, 2023
Received: September 29, 2023

Dear James Kenny:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Brian D. Pullin -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230418

Device Name
Mighty Wire Guide Wire

Indications for Use *(Describe)*
The Merit Mighty Wire is intended to be used to facilitate the placement of devices during diagnostic and interventional procedures in the central circulatory system, excluding the coronary arteries and 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(+353) 91 703798
	Fax Number:	(+353) 91 680104
	Contact Person:	James Kenny
	Registration Number:	1721504
	Correspondent Name:	Merit Medical Ireland Ltd.
	Address:	Parkmore Business Park Parkmore, Galway, Ireland
	Telephone Number:	(+353) 91 703798
	Fax Number:	(+353) 91 680104
	Contact Person:	James Kenny
	Date of Preparation:	14 February 2023
	Registration Number:	9616662
Subject Device	Trade Name:	Mighty Wire Guide Wire
	Common/Usual Name:	Guide Wire
	Class:	II
	Product code:	DQX
	Classification Name:	Wire, Guide, Catheter
	Regulation Number:	21 CFR 870.1330
	Regulation Medical Specialty	Cardiovascular
Predicate Device	Trade Name:	Lunderquist Extra-Stiff Wire Guide
	Class:	II
	Product code:	DQX
	Classification Name:	Wire, Guide, Catheter
	Regulation Number:	21 CFR 870.1330
	Regulation Medical Specialty	Cardiovascular
	Premarket Notification:	K220137
	Manufacturer:	Cook Medical

510(k) Summary

Device Description	The Merit Mighty Wire Guide Wire family all have 0.035” outer diameter with length configurations available in 90, 145, 180, 230, 260, and 300cm. The distal tip configurations are Straight, Curved (7.5mm J Radius), Double Curved (75mm/15mm Radius), and Extended Double Curved (55mm/15mm Radius). The wire is composed of a PTFE (polytetrafluoroethylene) coated stainless-steel core wire with a grind profile ending in a flexible distal tip. A PTFE coated stainless steel distal coil is laser-welded to the proximal end of the core wire grind profile and plasma arc-welded to the distal end of the core wire profile. The PTFE coating covers 100% of the guide wire surface. For wire lengths 230, 260, and 300cm, an additional radiopaque Platinum-Tungsten marker coil is welded to the core wire flexible distal tip. The distal tip is radiopaque.
Intended Use	The Merit Mighty Wire is intended to be used to facilitate the placement of devices during diagnostic and interventional procedures in the central circulatory system, excluding the coronary arteries and neurovasculature.

510(k) Summary

	The technological characteristics of the subject Merit Mighty Wire Guide Wire are substantially equivalent to those of Predicate Device, Lunderquist Extra-Stiff Wire Guide [K220137]. The Merit Mighty Wire Guide Wire was developed based on a full characterization of the Lunderquist Extra-Stiff Wire Guide: The wire is composed of a PTFE (polytetrafluoroethylene) coated stainless-steel core wire with a grind profile ending in a flexible distal tip. A PTFE coated stainless steel distal coil is laser-welded to the proximal end of the core wire grind profile and plasma arc-welded to the distal end of the core wire profile. The PTFE coating covers 100% of the guide wire surface. For wire lengths 230, 260, and 300cm, an additional radiopaque Platinum-Tungsten marker coil is welded to the core wire flexible distal tip. The distal tip is radiopaque.
Comparison to Predicate	The subject device has the same basic design as the predicate. The Lunderquist Extra-Stiff Wire Guide is comprised of a PTFE coated stainless-steel core wire and a PTFE coated stainless-steel coil. The PTFE coated coil is welded to the core on the very distal tip. Wires with lengths 260 and 300cm include an inner gold radiopaque coil. The fundamental technology and operating principles of the subject and the predicate are the same. While the indications for use wordings are not identical, both are intended to facilitate the placement of devices during diagnostic and interventional procedures. The Mighty Wire is for use in the “central circulatory system, excluding the coronary arteries and neurovasculature”. The Lunderquist Extra-Stiff Wire Guide is for use in the “major vessels, the aorta and vena cava, including their access vessels and adjacent vessels”. The intended use is the same for both the subject Mighty Wire Guide Wire and predicate Lunderquist Extra-Stiff Wire Guide, with both used for the placement and exchange of devices during 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 Mighty Wire 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” – October 2019
- FDA Guidance – “Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations” – October 2019
- FDA Guidance – “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile” – January 2016
- FDA Guidance – “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" – September 2020
- ISO 11070:2014/Amd.1:2018, Sterile single-use intravascular introducers, dilators and guidewires
- ISO 11135:2014/Amd 1:2018, Sterilization of health-care products — Ethylene oxide: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11737-1:2018/Amd 1:2021, Sterilization of health care products — Microbiological methods — — Part 1: Determination of a population of microorganisms on products
- ISO 10993-4:2017, Biological evaluation of medical devices—Part 4: Selection of tests for interactions with blood
- ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021, Biological evaluation of medical devices – Part 10: Tests for skin sensitization
- ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity

510(k) Summary

- ISO 10993-12:2021, Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
- ISO 10993-18:2020, Biological evaluation of medical devices – Part 18: Chemical characterization of materials
- ISO 10993-19:2020, Biological evaluation of medical devices – Part 19: Physico-chemical, morphological, and topographical characterization of materials
- ISO 10993-23:2021, Biological evaluation of medical devices – Part 23: Tests for irritation
- ASTM F2475-20, Standard Guide for Biocompatibility of Medical Device Packaging Materials
- ISO 10993-7:2008/Amd.1:2019(E), Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
- ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
- ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems
- ANSI ST72:2019, Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing
- ISO 2233:2000, Packaging – Complete, filled transport packages and unit labels – Conditioning for testing
- TIR42:2021, Evaluation of Particulates Associated with Vascular Medical Devices
- TIR28:2016, Product adoption and process equivalence for ethylene oxide sterilization

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

510(k) Summary

Performance Non-Clinical Testing-Bench

- Dimensional Verification
- Surface Finish
- Particulate Evaluation
- Coating Lubricity
- Fracture Test
- Flexing Test
- Guidewire Tip Radiopacity
- Guidewire Joints Tensile Strength
- Guidewire Torque Strength
- Corrosion Resistance
- Tip Flexibility
- Kink Resistance
- Coating Integrity
- Ancillary Device Compatibility
- Guidewire Preparation
- Guidewire Maneuverability in Catheter
- Tracking and Positioning Ancillary devices
- Guidewire Integrity
- J-Straightener Function
- Guidewire Body Stiffness
- Guidewire Distal Tip Flexibility
- Guidewire Trackability
- Guidewire Tip Shape Retention

Biocompatibility

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Hemocompatibility
    - Hemolysis
    - Thrombogenicity

510(k) Summary

	○ Complement Activation All test results were comparable to the predicate device and the subject Merit Mighty Wire Guide Wire met the predeterminded acceptance criteria.This demonstrated that the subject device is substantially equivalent to the predicate device.
Summary of Substantial Equivalence	Based on the comparisons noted, the subject Merit Mighty Wire Guide Wire meets the requirements that are considered essential for its intended use and is substantively equivalent to the Predicate Device, the Lunderquist Extra-Stiff Wire Guide [K220137] manufactured by Cook Medical.