December 10, 2024

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

Re: K241521
Trade/Device Name: Prelude Small O.D. Introducer Guide Wire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: May 29, 2024
Received: May 29, 2024

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Samuel G. Raben -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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241521

Device Name
Prelude Small O.D. Introducer Guide Wire

Indications for Use *(Describe)*
The Prelude Small O.D. Introducer Guide Wire is intended to facilitate the placement of introducer sheaths during diagnostic and interventional procedures.
The Prelude Small O.D. Introducer Guide Wire is indicated for use in the peripheral vasculature only.

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.

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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:	May 29, 2024
	Registration Number:	9616662
Subject Device	Premarket Notification:	K241521
	Trade Name:	Prelude® Small O.D. Introducer 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:	Predicate® Uncoated Guidewire
	Class:	II
	Product code:	DQX
	Classification Name:	Wire, Guide, Catheter
	Regulation Number:	21 CFR 870.1330
	Regulation Medical Specialty	Cardiovascular
	Premarket Notification:	K770977
	Manufacturer:	Integer® Holdings Corporation

510(k) Summary

Device Description	The Prelude® Small O.D. Introducer Guide Wire is composed of a stainless-steel core wire inside a stainless-steel coil. The guide wire is welded at the distal and proximal tips and has a polished weld finish. The stainless-steel construction provides radiopacity and visibility to the user under X-ray. The wires are available in outer diameters 0.018", 0.021" and 0.025", lengths from 45 cm to 80 cm, straight and double-ended J 3mm / straight tip shapes, Standard and Firm body wire stiffness profiles, with a flexible atraumatic tip.
Intended Use/ Indications for Use	The Prelude Small O.D. Introducer Guide Wire is intended to facilitate the placement of introducer sheaths during diagnostic and interventional procedures. The Prelude Small O.D. Introducer Guide Wire is indicated for use in the peripheral vasculature only.
Comparison to Predicate	The subject Prelude Small O.D. Introducer Guide Wire has a similar design and materials of construction. There is no difference in intended use or differences in technological characteristics between the subject device and predicate device: Both the subject device and predicate device are composed of stainless-steel core wire with a grind profile ending in a flexible distal tip. Both have a stainless-steel coil attached at the proximal end and distal end to the core wire. The wires have equivalent wire lengths, wire outer diameters, and wire tip configurations. Neither has a safety wire or coating. The fundamental technology and operating principles of the subject device and the predicate device are the same. Both are used to facilitate the placement of devices during peripheral diagnostic and interventional procedures.
Safety & Performance Tests	No applicable mandatory performance standards or special controls exist for the subject device. A battery of testing was conducted, on the Prelude Small O.D. Introducer Guide Wire, in accordance with test protocols based on requirements outlined in FDA Guidances and industry standards and these were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence. The following testing was successfully completed to demonstrate that the device meets the performance requirements for its intended use:

510(k) Summary

Non-Clinical Performance Testing

- Dimensional Verification/Size Designation
- Guide Wire J-Tip Straightening
- Surface Finish
- Fracture Test
- Flexing Test
- Guidewire Radiopacity
- Guidewire Joints Tensile Strength
- Guidewire Torque Strength
- Corrosion Resistance
- Tip Flexibility
- Kink Resistance
- Simulated Use Testing

Biocompatibility Testing

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

The subject Prelude Small O.D. Introducer Guide Wire met the predeterminded acceptance criteria and showed a performance comparable to the predicate device. This demonstrated that the Prelude Small O.D. Introducer Guide Wire subject device is substantially equivalent to the Predicate Uncoated Guidewire predicate device.

Summary of Substantial Equivalence	The subject Prelude Small O.D. Introducer Guide Wire is substantially equivalent in intended use, function, materials, method of operation, and performance to the Predicate Uncoated Guidewire (K770977) manufactured by Integer Holdings Corporation.