April 25, 2025

Merit Medical Systems, Inc.
Niloufar Samimi
Senior Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K250909
Trade/Device Name: Prelude Wave Hydrophilic Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 26, 2025
Received: March 26, 2025

Dear Niloufar Samimi:

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,

Misti L. Malone -S

Misti Malone
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)*
K250909

Device Name
Prelude Wave Hydrophilic Sheath Introducer

Indications for Use *(Describe)*
The Merit Prelude Wave Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries, including but not limited to the radial artery, while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.
The access needle with inner metal needle and outer plastic cannula is used to gain access to the vein or artery for placement of guidewires.

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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"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:	(385) 534-0632
	Contact Person:	Niloufar Samimi
	Date Prepared:	03/25/2025
	Registration Number:	1721504
Subject Device	Trade Name:	Prelude Wave Hydrophilic Sheath Introducer
	Common/Usual Name:	Sheath Introducer
	Classification Name:	Catheter Introducer
	Regulatory Class:	2
	Product Code:	DYB
	21 CFR §:	870.1340
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	Prelude IDeal Hydrophilic Sheath Introducer
	Common/Usual Name:	Sheath Introducer
	Premarket Notification:	K173750
	Manufacturer:	Merit Medical Systems, Inc.
	This predicate has not been subject to a design-related recall.	

Device Description	The Prelude Wave™ Hydrophilic Sheath Introducer consists of a sheath introducer with compatible vessel dilator that snaps securely into the sheath introducer hub. The sheath hub contains an integral hemostasis valve. The sheath tubing is coated with a hydrophilic coating. A sidearm is affixed to the sheath hub and has a 3-way stopcock at its proximal end. The Prelude Wave™ Hydrophilic Sheath Introducer is available in 11cm and 23cm lengths, (French sizes 4F, 5F, 6F and 7F) and is designed to accept 0.018", 0.021" and 0.025" diameter guidewires. The Prelude Wave™ Hydrophilic Sheath Introducer is marketed with any of the following components, depending on the product configuration: guidewire, metal access needle, access needle with inner metal needle and outer plastic cannula and SnapFix™ securement device.
Indications for Use	The Merit Prelude Wave Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries, including but not limited to the radial artery, while maintaining hemostasis for a variety of diagnostic and therapeutic procedures. The access needle with inner metal needle and outer plastic cannula is used to gain access to the vein or artery for placement of guidewires.

	The design and technological characteristics of the subject modified Prelude Wave are substantially equivalent to those of the predicate Prelude IDEAL. The subject device has the same basic design as the predicate device. The differences between the predicate Prelude IDEAL device and the subject/modified Prelude Wave device are as follows: • Sheath material. • Modified sheath/dilator tip and fit. • Packaged with adhesive backed fixation device to keep the sheath in place throughout the procedure.
Comparison to Predicate Device	The comparison between the subject and the predicate devices is based on the following: • Same intended use • Same indications for use • Same sterilization methods • Same packaging scheme • Same fundamental technology/principles of operation • Similar material types (all meet ISO 10993 biocompatibility requirements) • Equivalent design

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject Micro Ace™ Gold was conducted based on the risk analysis - and based on the requirements of the following international standards:

1. ISO 10555-1:2013, *Intravascular Catheters – Sterile and single-use catheters – Part 1: General requirements.*
2. EN ISO 11070 2014/A1:2018, *Sterile Single-Use Intravascular Catheter Introducers.*
3. ISO 10993-1:2018, *Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process*, and FDA guidance *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*. The appropriate tests were performed for the classification: *Externally Communicating Device with Circulating Blood Contact for a Limited Duration (≤ 24 hours).*
4. ISO 14971:2019, *Medical Devices – Application of Risk Management to Medical Devices.*

Performance tests

The tests listed below were performed to demonstrate that the modified device meets product specification criteria, and to demonstrate there were no unacceptable risks associated with the changes made to the device.

The tests were performed on both 4F and 7F Prelude Wave products. The verification studies were performed on devices at baseline (t=0) and shelf-life (following 6-month accelerated aging).

<u>Design Verification Studies</u>

- Standard Insertion Force Sheath
- Standard insertion force-Dilator
- Dilator tip flaring (characterization only)
- Sidewall compression
- Sheath shaft Tensile
- Pushability/kink Resistance
- Sheath Hub Torque (characterization only)
- Sheath Hub Tensile
- Dilator Hub Tensile
- Distance from Sheath to Dilator Tip
- Dilator OD
- Sheath OD

- Lubricity 5 & 20 Cycle
- Coating Ratio
- Average Drag test
- Dry out (characterization only)
- Leak test
- Dilator Tipped ID
- Sheath Tipped ID
- Sheath Effective Length
- Dilator tip flaring- duplicate
- Curved insertion Force (characterization only)
- Radiopacity
- Hydrophilic Coating Area
- Coating length
- Particulate test

SnapFix

- Grooved ring/fixation rotation
- Ink adherence/legibility
- Vertical clip force (characterization only)
- Horizontal Clip removal force
- Adhesive Removal Force
- Grooved ring removal force

Design Validation Studies

- Clinician feedback following assessment of design changes.

Biocompatibility Studies

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systematic Toxicity
- Pyrogenicity
- Hemolysis (direct and indirect contact)
- Partial Thromboplastin Time
- Thrombogenicity (blood loop assay)
- Heparinized Blood Platelet and Leukocyte Count
- Complement Activation

Summary of Substantial Equivalence

Based on the indications for use, design, materials, safety and performance testing (verification and validation), and materials, the subject Prelude Wave is deemed to be *substantially equivalent* to the predicate device, the Prelude IDEAL, K173750. Both the subject device and the predicate device are legally manufactured by Merit Medical Systems, Inc.