October 4, 2021

Merit Medical Systems, Inc.
David Thomas
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, Utah 84095

Re: K211405
Trade/Device Name: Prelude Guide Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB, DRE
Dated: August 31, 2021
Received: September 1, 2021

Dear David Thomas:

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,

Finn Donaldson
Assistant Director (Acting)
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)*
K211405

Device Name
Prelude® Guide Sheath

Indications for Use *(Describe)*
The Prelude Guide Sheath Introducer is indicated to be used for the introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.

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.

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510(k) Summary

K211405

Prelude Guide Sheath

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 316-4956
	Fax Number:	(801) 208-3365
	Contact Person:	David Thomas
	Date of Preparation:	August 31, 2021
	Registration Number:	1721504
Subject Device	Trade Name:	Prelude® Guide Sheath
	Common/Usual Name:	Sheath Introducer
	Classification Name:	Catheter Introducer
Predicate Device	Trade Name:	DuraSheath Introducer Sheath System
	Classification Name:	Catheter Introducer
	Premarket Notification:	K181463 (Predicate)
	Manufacturer:	Contract Medical International
		K091329 (Reference Device) – Pinnacle Destination Peripheral Guiding Sheath
	Manufacturer:	Terumo Medical Corp
Classification	Class II 21 CFR § 870.1340 FDA Product Code: DYB, DRE Review Panel: Cardiovascular	

Indications for Use	The Prelude Guide Sheath Introducer is indicated to be used for the introduction of interventional and diagnostic devices into the peripheral (and coronary) vasculature.

A. Device Description

The Prelude Guide Sheath Introducer is a sterile, disposable device consisting of a (a) a coil reinforced shaft with an atraumatic tip and the distal end: (b) a hemostasis valve with a side port and color-coded stopcock; and (c) a tapered tip dilator with snap-fit hub at the proximal end.

(a) **Shaft.** The coil reinforced, multi-layer polymer shaft contains a tapered tip at the distal end. A continuous inner PTFE tube forms the core of the shaft and provides a circular working lumen through which devices can be passed. A single, full length Pebax tube creates the outer cover of the shaft. A stainless-steel flat wire coil is fused between the two polymer tubes along the entire length of the shaft. Hydrophilic coating is applied on the distal 35cm of the shaft. A radiopaque marker made of platinum iridium is embedded 5mm from the distal end of the shaft. At the proximal end of the shaft, a female, winged luer hub is over-molded onto the shaft to support handling and to provide for the connection of the hemostasis valve. This hub is color coded to match the French size of the device.

(b) **Hemostasis valve.** A removable hemostasis valve is thread onto the luer hub at the proximal end of the shaft. Inside the valve housing, a lubricated, silicone slit disc provides a seal around devices passed through the sheath, thereby preventing blood leakage through the valve. Just distal of the valve, the valve housing is connected to a side port leading to a three-way stopcock valve. The sideport is used for flushing the introducer sheath. At the proximal end of the valve housing, the color-coded housing cap provides a snap fit connection the hub of the dilator.

(c) **Dilator.** The dilator made of a polypropylene blend with Pebax and Barium sulphate (4F) or polypropylene blend with Bismuth Oxychloride (5-8F) contains a full-length round lumen to allow placement over guidewire. The distal end of the dilator is configured as a tapered tip that extends about 2 cm beyond the end of the sheath when the dilator is fully inserted through the sheath. An integral, color coded luer hub that is over-molded onto the proximal end the dilator supports handling of the dilator and provides a snap fit connection to the valve housing cap at the proximal end of the sheath introducer.

B. Operation and Compatibility

After removal from the sterile pouch packaging using aseptic techniques, the device is placed into the vasculature. Prior to use, the introducer sheath and dilator are flushed with heparinized solution. The dilator is then inserted completely into the introducer sheath and locked into place through the snap fit connection at the housing of the hemostasis valve. The dilator-sheath-combination is then passed as one unit over a guide wire with a maximum size of up to 0.035 inches for 4 French and up to 0.038 inches for 5 French through 8 French models. Guide wire is not part of the device. Once the introducer sheath is fully placed in the patient, the guide wire and dilator are removed and compatible catheters and instruments can be inserted through the introducer sheath.

C. Device Models

The Prelude Guide Sheath consists of twenty-nine (29) models of different sizes (4 French, 5 French, 6 French, 7 French and 8 French) and effective lengths (45cm, 65cm and 90 cm).

D. Comparison of Technological Characteristics with the Predicate Devices

With regard to the design, device features, method of sterilization, and mode of operation, the Prelude Guide Sheath does not differ from the predicate devices. Materials used to manufacture the Prelude Guide Sheath are identical to that used in the legally marketed predicate device, or very similar to those contained in the legally marketed reference device.

Technological characteristics of the subject device do not differ from the predicate device and differ only with respect to materials for selected components and the choice of lubricious coating on the sheath from a hydrophobic coating to a hydrophilic coating which is similar to the reference device. Both the Pebax used for the outer layer and the hydrophilic coating applied to the distal end of the sheath of the Prelude Guide Sheath are commonly used in medical devices, including introducer sheaths and catheters. There are no differences in the material and technological characteristics between the subject device and the predicate device.

E. Performance Tests

Nonclinical performance data demonstrates that the Prelude Guide Sheath is substantially equivalent to the predicate. The following performance data from the non-clinical tests were provided to support the substantial equivalence determination:

- Manual testing, including tests required under relevant international standards, coating adhesion and particulate testing, transportation integrity testing, performed to verify the validate the design.
- Biocompatibility Risk Assessment (BRA) and biocompatibility device testing to demonstrate compatibility.
- Sterilization information to confirm sterility of the device upon exposure to the selected sterilization cycle.
- Accelerated aging testing to confirm product performance at end of shelf life.

The list of tests performed to support determination of substantial equivalence is provided in the table below.

Testing Performed

No,	Verification/Validation Test	Applicable Standard(s)
1	Insertion Force/Tip Insertion Peel Back	Internal Requirement
2	Peak Tensile Force Shaft/Hub & Tip	ISO 10555-1:2013 ISO 10555-3:2013 ISO 11070:2014
3	Visual (Extraneous/Surface Defects)	ISO 11070:2014
4	Sheath Stiffness	Internal Requirement
5	Sheath Kink	Tested through Validation
6	Radiopacity marker band & tip	ISO 11070:2014, ASTM F640-12 ISO 10555-1:2013
7	Hydrophilic coating durability & coverage/coating length	Internal Requirement
8	Hydrophilic Coating Lubricity	Tested through Validation
9	Coating integrity test (particulate evaluation)	ASTM F1877-16 Class II Special Controls Guidance for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters
10	Corrosion resistance	ISO 11070:2014
11	Sheath assembly leak	ISO 11070:2014
12	Hydrogen Peroxide Resistance	ISO 10555-1:2013 ISO 10555-3:2013
13	Radiopacity Dilator	ISO 11070:2014 ISO 10555-1:2013
14	Dilator tip fracture	Internal Requirement
15	Dilator-to-Hub Tensile	ISO 10555-1:2013
16	Sheath tip to dilator taper length	Internal Requirement
17	Dilator Stiffness & Hub Snap Force	No Standard-Tested through Validation

18	Dilator Insertion/Removal from Sheath	No Standard - Testing through Validation
19	Dimensional tests for OD & ID of sheath & dilator	ISO 11070:2014
20	Curve shape & visual for sheath & dilator	Internal Requirement
21	Curve Retention	No standard - Testing through Validation
22	Sheath Effective Length	ISO 10555-1:2013
23	Luer Design Tests	ISO 11070:2014 ISO 594-1: 1986 ISO 594-2:1998
24	Hemostasis Valve Leakage	ISO 11070:2014
25	EO Sterilization Validation	ISO 11135:2014 ISO 10993-7:2008 AAMI TIR28:2016
26	Package Integrity Testing	ISO 11607-1:2019 ISO 11607-2:2019 ASTM D4169-16
27	Biocompatibility Testing Cytotoxicity Testing Sensitization Irritation Acute Systemic Toxicity Pyrogenicity Hemocompatibility o ASTM Hemolysis Study – Direct Contact and Extract Method: Phosphate Buffered Saline Extraction	ISO 10993-1:2009 ISO 10993-4: 2017 ISO 10993-5:2009 ISO 10993-6:2009 ISO 10993-7:2008 ISO 10993-10:2010 ISO 10993-11:2017 ISO 10993-12:2012

	○ Complement Activation (SC5b-9 only) Assay Thrombogenicity Study – In-vitro Blood Loop Assay, Partial Thromboplastin Time (PTT)	
28	Chemical Characterization – Particulate Analysis	ASTM F1877-16

F. Conclusions

The results of the testing demonstrated that the subject Prelude Guide Sheath met the predetermined acceptance criteria applicable to the performance of the device.

Based on the indications for use, design, safety and performance testing, the subject Prelude Guide Sheath raises no new questions of safety and effectiveness compared to the predicate device and is substantially equivalent to the predicate device, DuraSheath Introducer Sheath System K181463 manufactured by Contract Medical International.