January 7, 2022

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

Re: K212152
Trade/Device Name: Prelude IDeal 9F Hydrophilic Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: December 3, 2021
Received: December 6, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212152

Device Name
Prelude IDeal 9F Hydrophilic Sheath Introducer

Indications for Use *(Describe)*
The 9F Prelude IDeal Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures.

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

K212152

9F Prelude IDeal Hydrophilic Sheath Introducer

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:	December 3, 2021
	Registration Number:	1721504
Subject Device	Trade Name:	9F Prelude IDeal™ Hydrophilic Sheath Introducer
	Common/Usual Name:	Sheath Introducer
	Classification Name:	Catheter Introducer
	Regulatory Class:	II
	Product Code:	DYB
	21 CFR §:	870.1340
	Review Panel:	Cardiovascular
Predicate Device	Trade Name:	9F Prelude IDeal™ Hydrophilic Sheath Introducer
	Classification Name:	Catheter Introducer
	Premarket Notification:	K173750
	Manufacturer:	Merit Medical Systems, Inc.
Reference Device	Tradename:	Flexor Check-Flo Introducers
	Classification Name:	Sheath Introducer
	Premarket Notification:	K142829
	Manufacturer:	Cook Incorporated
Classification	Class II 21 CFR § 870.1340 FDA Product Code: DYB, DRE Review Panel: Cardiovascular	

Indications for Use	The 9F Prelude IDeal Hydrophilic Sheath Introducer is intended to provide access and facilitate the percutaneous introduction of various devices into veins and/or arteries while maintaining hemostasis for a variety of diagnostic and therapeutic procedures

A. Device Description

The 9F Prelude IDeal 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. A rotating suture ring is affixed to the sheath hub. The sheath tubing is coated with a hydrophilic coating and incorporates a stainless steel braid. A sidearm is affixed to the sheath hub and has a 3-way stopcock at its proximal end.

The 9F Prelude Ideal Hydrophilic Sheath Introducer is available in 11cm and 23cm lengths, (French size 9F) and is designed to accept 0.038” diameter guide wires.

The 9F Prelude Ideal Hydrophilic Sheath Introducer is marketed with the following components: guide wire, metal access needle, guide wire insertion device.

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 0.038 inches. 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 9F Prelude IDeal™ Hydrophilic Sheath Introducer consists of two (2) models of different effective lengths (11cm and 23cm).

D. Comparison of Technological Characteristics with the Predicate Devices

The technological characteristics of the subject 9F Prelude Ideal Hydrophilic Sheath Introducer are substantially equivalent to those of the predicate 4F through 7F Prelude Ideal Hydrophilic Sheath Introducer. The subject device has the same basic design as the predicate device in that it consists of sheath tubing, hub, sidearm and stopcock and is provided with a vessel dilator. The difference between the subject and the predicate devices is the diameter of the sheath and dilator, the larger hemostasis valve and the colorants used on the strain relief, sheath cap, dilator hub and stopcock handle. There have also been changes to the currently marketed Prelude IDeal product lines that have also been included with this new 9F size that include 1) the sidearm tubing which changed the tubing material from Carbothane to Tecothane, 2) the removal of the compression sleeve, and 3) the change in dilator material from a homopolymer polypropylene to a copolymer polypropylene.

The indications for use for the 9F Prelude IDeal Hydrophilic Sheath Introducer is the same as the predicate Prelude IDeal Hydrophilic Sheath Introducer with the exemption of the following:

The indications for the 9F Prelude IDeal does not include a statement “including but not limited to the radial artery” since this larger size catheter is considered too large for safe use in the radial artery. The indication is the same as other Prelude Sheath introducers that include up to an 8F size such as the Prelude Sheath Introducer cleared under K070159 that are also not used for radial access.

The indications also does not include the statement “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” since this type of access needle is not included with the 9F size.

These changes are not critical to the intended surgical use of the product which can still be safely and effectively used for access to other peripheral veins or arteries.

E. Performance Tests

Nonclinical performance data demonstrates that the 9F Prelude IDeal™ 9F Hydrophilic Sheath Introducer consists 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, Sidearm & Tip	ISO 10555-1:2013 ISO 10555-3:2013 ISO 11070:2014
	Cap Tensile	Internal Requirement
3	Visual (Extraneous/Surface Defects)	ISO 11070:2014
	Sheath Tip Ball Gauge Drag	Internal Requirement
4	Sheath Stiffness	Internal Requirement
5	Sheath Kink	Internal Requirement
	Sidewall Compression	Internal Requirement
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	Internal Requirement
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
15	Dilator-to-Hub Tensile	ISO 10555-1:2013
16	Tip Bend Test	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
	Stiffness of introducer through tortuous path/ guidewire & catheter compatibility,	Tested through validation
20	Dilator Ink Adhesion	Internal Requirement
22	Sheath Effective Length	ISO 10555-1:2013
	Suture Ring Tensile/Rotation	ISO 11070:2014
	Dilator Drag through Sheath Valve & Tip	Internal Requirement
	Torque, Sheath Bend Radius,	No specification requirement
24	Hemostasis Valve Leakage/dislodgement	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 o Complement Activation (SC5b-9 only) Assay Thrombogenicity Study – In-vitro Blood Loop Assay, Partial Thromboplastin Time (PTT) Heparinized Blood Platelet and Leukocyte Count Assay	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
28	Chemical Characterization – Particulate Analysis	ASTM F1877-16

F. Conclusions

The results of the testing demonstrated that the subject 9F Prelude IDeal™ Hydrophilic Sheath Introducer 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 9F Prelude IDeal™ 9F Hydrophilic Sheath Introducer raises no new questions of safety and effectiveness compared to the predicate device and is substantially equivalent to the predicate device, Prelude IDeal™ Hydrophilic Sheath Introducer manufactured by Merit Medical Systems, Inc. (K171750).