February 15, 2018

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

Re: K173750
Trade/Device Name: Prelude IDeal Hydrophilic Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 15, 2018
Received: January 16, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173750

Device Name
Prelude IDeal Hydrophilic Sheath Introducer

Indications for Use *(Describe)*
The Merit Prelude IDeal 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 guide wires.

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.

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510(k) Summary – K173750

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) 253-6982
	Contact Person:	David Thomas
	Date of Preparation:	January 15, 2018
	Registration Number:	1721504
Subject Device	Trade Name:	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:	PreludeEASE™ Hydrophilic Sheath Introducer
	Classification Name:	Sheath Introducer
	Premarket Notification:	K140543 (Primary Predicate Device) K150257 (Secondary Predicate Device)
	Manufacturer:	Merit Medical Systems, Inc.
	This predicate has not been subject to a design-related recall.	
Device Description	The 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 Prelude Ideal Hydrophilic Sheath Introducer is available in 7cm, 11cm, 16cm and 23cm lengths, (French sizes 4F, 5F, 6F and 7F) and is designed to accept 0.018”, 0.021” and 0.025” diameter guide wires. The Prelude Ideal Hydrophilic Sheath Introducer is marketed with any of the following components, depending on the product configuration: guide wire, metal access needle, access needle with inner metal needle and outer plastic cannula and BowTie™ guide wire insertion device.	

Indications for Use	The Merit Prelude IDeal 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 guide wires.
Comparison to Predicate Device	The technological characteristics of the subject Prelude Ideal Hydrophilic Sheath Introducer are substantially equivalent to those of the predicate 4F through 7F PreludeEASE 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 in the materials used for the sheath that allow for a thinner wall sheath than the predicate devices and the colorants used on the strain relief, sheath cap and stopcock handle.

Performance Tests

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject 7F Prelude IDeal Hydrophilic Sheath Introducer was conducted based on the risk analysis and based on the requirements of the following international standard:

- ISO 11070:1998, *Sterile, single-use intravascular catheter introducers*
- ISO 11135:2014*, Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 10993-1:2009, *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*, May 1, 1995
- ISO 10993-3:2014, *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity*
- ISO 10993-4:2002 (Amd.1:2006)*, Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*
- ISO 10993-5:2009*, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
- ISO 10993-7:2008, *Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals*
- ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*
- ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*
- ASTM F756-17, *Standard practice for assessment of hemolytic properties of materials*
- United States Pharmacopeia 40, National Formulary 35, 2017 <151> Pyrogen Test

The following tests were performed to demonstrate there were no unacceptable risks associated with the changes made to the device:

Performance Testing - Bench

- Suture Ring Rotation
- 90º Tip Bend Test/Conditioning
- Tensile – Tip to Shaft
- Sheath Assembly Leak, 300kPa
- Tensile – Hub to Sidearm (4F only)
- Tensile – Valve Cap to Hub

Performance Tests cont.

- Tensile – Suture Ring to Strain Relief
- Dilatory Drag through Sheath Tip and Valve
- Sheath Effective Length
- Kink – Dual Pivot
- Stiffness, Force of Deflection
- Sidewall Compression
- Tip Insertion Force (with coating activation)
- Coating Lubricity and Durability
- Sheath Bend Radius
- Radiopacity of Shaft and Tip
- Hydrophilic Coating Uniformity, Coverage Length
- Tensile – Hub to Shaft
- Sheath Tip Ball Gauge Drag
- Sheath Shaft Inner Diameter
- Sheath Shaft Outer Diameter
- Tensile – Shaft
- Torque – Shaft to Hub
- Corrosion Resistance
- Particulate Evaluation

<u>Validation Testing</u>

- Outer Surface
- Stiffness with Dilator
- Catheter Insertion and Exchange
- Sheath Stiffness without Dilator

<u>Biocompatibility</u>

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

	The results of the testing demonstrated that the subject Prelude IDeal Hydrophilic Sheath Introducer met the predetermined acceptance criteria applicable to the performance of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, and performance testing, the subject Prelude IDeal Hydrophilic Sheath Introducer raises no new questions of safety or effectiveness compared to the predicate device and is substantially equivalent to the predicate device, the PreludeEASE Hydrophilic Sheath Introducer, K140543 and K150257, manufactured by Merit Medical Systems, Inc.