DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 30, 2015

Merit Medical Systems, Inc.
Alina Stubbs
Regulatory Affairs Specialist II
65 Great Valley Parkway
Malvern, Pennsylvania 19355

Re: K152381
Trade/Device Name: Prelude SNAP™ Splittable Hydrophilic Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 30, 2015
Received: October 1, 2015

Dear Alina Stubbs:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152381

Device Name

Prelude SNAP™ Hydrophilic Splittable Sheath Introducer

Indications for Use *(Describe)*

For the introduction of various types of pacing leads and catheters to the heart and coronary venous system.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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K152381 510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	65 Great Valley Parkway Malvern, PA 19335
	Telephone Number:	(610) 651-5046
	Fax Number:	(801) 545-4285
	Contact Person:	Alina Stubbs
	Date of Preparation:	October 27, 2015
	Registration Number:	2529252
Subject Device	Trade Name:	Prelude SNAP™ Splittable Hydrophilic Sheath Introducer
	Common/Usual Name:	Sheath Introducer
	Classification Name:	Introducer, Catheter (21 CFR §870.1340)
Predicate Device	Trade Name:	Prelude SNAP™ Splittable Sheath Introducer
	Classification Name:	Introducer, Catheter (21 CFR §870.1340)
	Premarket Notification:	K143255 - Prelude SNAP™ Splittable Sheath Introducer
	Manufacturer:	Merit Medical Systems, Inc.
Classification	Class II 21 CFR § 870.1340 FDA Product Code: DYB Review Panel: Cardiovascular	
Intended Use	Prelude SNAP™ Splittable Hydrophilic Sheath Introducer is indicated “For the introduction of various types of pacing leads and catheters to the heart and coronary venous system”.	

Device Description

Prelude SNAP™ Splittable Hydrophilic Sheath Introducer is a splittable hemostatic introducer system that is intended for the introduction of various types of pacing leads and catheters. The Prelude SNAP™ Splittable Hydrophilic Sheath Introducer system consists of a splittable sheath introducer lubricated with hydrophilic coating, dilator, 18g introducer needle, guide wire, and a syringe. The device is provided sterile and intended for single use only. It is for use in hospitals or healthcare facilities.

The splittable sheath introducer contains a hemostasis valve to minimize blood loss and air ingress during use. The introducer is available with a side-port and three-way stopcock that provides means for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The splittable sheath introducer is available in two lengths: 13cm and 25cm. The dilator is designed to conform to the inner diameter of the introducer and has a tapered tip.

The materials of construction are primarily polymers with the exception of the guide wire and needle cannula which are stainless steel.

Comparison to Predicate Device

Summary of the technological characteristics of the modified device compared to the predicate device:

Technical Characteristics	Predicate Device (K143255)	Subject Device
Device Dimensions (nominal)		
Sheath introducer inner diameter (French)	6F through 12.5F	6F through 12.5F
Sheath introducer length (cm)	13 & 25 cm	13 & 25 cm
Sheath Introducer sideport and stopcock	Available with and without sideport and stopcock.	Available with sideport and stopcock only.
Dilator outer diameter (French)	6F through 12.5F	6F through 12.5F
Dilator length (in)	13 cm: 8.34” and 25 cm: 13.09”	13 cm: 8.34” and 25 cm: 13.09”
Dilator tip ID (in)	0.039”	0.039”
Introducer needle length (cm)	7 cm	7 cm
Introducer needle outer diameter (gage)	18 g	18 g
Guide wire length & diameter (in. x cm)	13 cm: 0.038” x 50 cm J-Tip and 25 cm: 0.038” x 80 cm J-Tip	13 cm: 0.038” x 50 cm J-Tip and 25 cm: 0.038” x 80 cm J-Tip
Syringe volume (cc)	12 cc or 10 cc	12 cc or 10 cc
Device Materials		
Sheath Lubricant	Silicone Dispersion	Hydrophilic Coating
All other materials of the Prelude SNAP™ Splittable Hydrophilic Sheath Introducer are identical to the predicate device.		

Note: All dimensions are nominal.

Safety & Performance Tests

The Prelude SNAP™ Splittable Hydrophilic Sheath Introducer has been thoroughly tested through verification of product specifications and user requirements. The following quality assurance measures were applied during the development of the Prelude SNAP™ Splittable Hydrophilic Sheath Introducer:

- Risk Analysis
- Requirements/Specification Reviews
- Design Reviews
- Performance Testing-Bench
    - Introducer Sheath Insertion
    - Introducer Sheath Outer Diameter (O.D.)
    - Introducer Sheath Tip Inner Diameter (I.D.)
    - Introducer Sheath Peel Force
    - Simulated Use – Introducer Insertion (Kink and Flexibility)
    - Introducer Sheath – Coating Length
    - Introducer Sheath – Coating Adherence
    - Introducer Sheath – Coating Lubricity/Durability
    - Particulate Testing
- Sterilization Validation
- Biocompatibility Testing
    - Cytotoxicity

Safety & Performance Tests (continued)	No performance standards have been established under section 514 of the Food, Drug and Cosmetic Act for this device. When applicable, performance testing of the Prelude SNAP™ Splittable Hydrophilic Sheath Introducer was conducted based on the risk analysis and based on the requirements of the following international standards: • ISO 11070:1998E Sterile single-use intravascular catheter introducers • ISO 11135-1: 2007, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices • AAMI TIR28:2009, Product adoption and process equivalence for ethylene oxide sterilization • ISO 10993-1: 2009, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process, • ISO 10993-7: 2008, Biological Evaluation of Medical Devices Part-7 Ethylene Oxide Sterilization Residuals • USP 37-NF 32 <85>, United States Pharmacopeia 37, National Formulary 32, 2014 <85> Bacterial Endotoxins Test • USP 37-NF 32 <151>, United States Pharmacopeia 37, National Formulary 32, <151> Pyrogen Test. 2014 • AAMI/ANSI ST72:2011, Bacterial Endotoxins – Test methods, routine monitoring, and alternatives to batch testing • ASTM D4169-09, Standard Practice for Performance Testing of Shipping Containers and Systems • ISO 11607-1: 2009, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems • ISO 14971:2012, Medical devices – Application of risk management to medical devices The results of the testing demonstrated that the subject Prelude SNAP™ Splittable Hydrophilic Sheath Introducer met the predetermined acceptance criteria of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Prelude SNAP™ Splittable Hydrophilic Sheath Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Prelude SNAP™ Splittable Sheath Introducer - K143255, manufactured by Merit Medical Systems, Inc.