DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 16, 2014

Merit Medical Systems, Inc.
Ms. Michaela Rivkowich
Principal Regulatory Affairs Specialist
1600 West Merit Pkwy.
South Jordan, Utah 84095

Re: K140543
Trade/Device Name: PreludeEase Hydrophilic Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 3, 2014
Received: September 4, 2014

Dear Ms. Rivkowich,

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,

Melissa A. Torres -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140543

Device Name
PreludeEASE Hydrophilic Sheath Introducer

Indications for Use *(Describe)*
The Merit PreludeEASE 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)

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.

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510(k) Summary

General Provisions	Submitter Name: Address: Telephone Number: Fax Number: Contact Person: Date of Preparation: Registration Number:	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095 (801) 208-4196 (801) 253-6932 Michaela Rivkowich October 16, 2014 1721504
Subject Device	Trade Name: Common/Usual Name: Classification Name:	PreludeEASE™ Hydrophilic Sheath Introducer Sheath Introducer Catheter Introducer
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Prelude® PSI Sheath Introducer Vessel Dilator for Percutaneous Catheterization K070159 Merit Medical Systems, Inc.
Predicate Device	Trade Name: Classification Name: Premarket Notification: Manufacturer:	Glidesheath Catheter Introducer K102008 Terumo Medical Corporation
Classification	Class II 21 CFR § 870.1340 FDA Product Code: DYB Review Panel: Cardiovascular	
Intended Use	The Merit PreludeEASE™ 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 or 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.	

Device Description	The PreludeEASE™ Hydrophilic Sheath Introducer consists of a sheath introducer with compatible vessel dilator that snaps securely into the sheath introducer hub. The sheath is coated with a hydrophilic coating and is equipped with a sidearm terminating in a 3-way stopcock. The sheath hub contains an integral hemostasis valve and suture ring. The access needle with inner metal needle and outer plastic cannula is an accessory device which is used to gain access to the vein or artery for placement of guide wires. The PreludeEASE 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, syringe, scalpel and BowTie™ guide wire insertion device.
Comparison to Predicate Device	The technological characteristics of the subject PreludeEASE Hydrophilic Sheath Introducer are substantially equivalent to those of the predicate devices. The subject device has the same basic design as the predicate devices in that it consists of a sheath tubing, hub, sidearm and stopcock and is provided with a vessel dilator. The main difference is in the device materials. Just as the predicate devices, the PreludeEASE is provided with kit components typically used to obtain vascular access.

Safety & 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 PreludeEASE 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 11135-1:2007*, Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
- ISO 11607-1:2010, *Packaging for terminally sterilized medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems*
- ASTM D4169-09, *Standard Practice for performance Testing of Shipping Containers and Systems*
- ISO 2233:2000, *Packaging – Complete, filled transport packages and unit loads – Conditioning for testing*
- 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
- ANSI/AAMI/ISO 10993-3:2003, *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 F756-08, *Standard practice for assessment of hemolytic properties of materials*
- United States Pharmacopeia 35, National Formulary 30, 2012 <151> Pyrogen Test

Safety & Performance Tests cont.	Performance Testing-Bench • Surface • Radiodetectability • Size Designation • Sheath Introducer Assembly Leak • Sheath Introducer Hemostasis Valve 5.8 psi Leak • Sheath Introducer Tubing Pull (Force at Break) • Sheath Introducer Hub to Tubing Pull (Force at Break) • Dilator Hub to Tubing Pull (Force at Break) • Sheath / Dilator Tip Peel Back • Hemostasis Valve Dislodgement • Hemostasis Valve Vacuum • Hemostasis Valve Low Pressure with Dilator Dwell • Sidearm to Sheath Hub Pull (Force at Break) • Sheath Hub to Cap Pull (Force at Break) • Sheath Introducer Stiffness and Flex Modulus • Sheath Introducer Kink Resistance • Suture Ring Pull Test • Dilator Stiffness and Flex Modulus • Hydrophilic Coating Lubricity • Hydrophilic Coating Coverage/Adherence and Length • Two-Part Access Needle Metal Cannula to Hub Pull • Two-Part Access Needle Plastic Cannula to Hub Pull • Two-Part Access Needle Insertion and Withdrawal Test • Particulate Evaluation • Kink Resistance • Torque Strength • Packaging Testing • Scalpel Flex Test Biocompatibility • Cytotoxicity • Sensitization • Intracutaneous Injection • Acute Systemic Toxicity • Pyrogenicity • Genotoxicity • Hemolysis • Thrombogenicity • Complement Activation • Chemical Characterization

Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject PreludeEASE Hydrophilic Sheath Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate devices, the Prelude PSI Sheath Introducer, K070159 and the Glidesheath, K102008.