Prelude® 7F Short Sheath Introducer
Section 5, 510(k) Summary
Special Premarket Notification 510(k)

AUG 17 2012

Section 5

510(k) Summary

General Provisions	Submitter Name:	Merit Medical Systems, Inc.
	Address:	1600 West Merit Parkway South Jordan, UT 84095
	Telephone Number:	(801) 316-4831
	Fax Number:	(801) 826-4113
	Contact Person:	Dan Clark
	Date of Preparation:	July 23, 2012
	Registration Number:	1721504
Subject Device	Trade Name: Prelude® 7F Short Sheath Introducer Common/Usual Name: Introducer Catheter Classification Name: Introducer, Catheter	
Predicate Device	Trade Name: Prelude® Short Sheath Introducer Classification Name: Introducer, Catheter Premarket Notification: K082063 Manufacturer: Merit Medical Systems, Inc.	
Classification	Class II 21 CFR § 870.1340 FDA Product Code: DYB Review Panel: Cardiovascular	
Intended Use	The Prelude® 7F Short 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. This device can also provide access to a native or synthetic graft used for hemodialysis. The side port of the sheath allows adequate flow to perform temporary hemodialysis. The device is not indicated for long term vascular or hemodialysis access.	

Device Description	The Prelude® 7F Short Sheath Introducer consists of a sheath introducer with integral hemostasis valve and side port extension tubing extending from the sheath hub. A detachable 3-way stopcock is connected to the side port extension tubing. A compatible vessel dilator is provided with the introducer. The device is available in 7F size with a sheath tubing length of 11cm. The French size designates the size of the catheter the sheath will accept. The 11cm effective length of the sheath introducer refers to the usable length of the sheath. The French size and wire tip size are printed on the dilator hub indicating the size of the catheter and guide wire that the sheath will accept.
Comparison to Predicate Device	The subject device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as predicate device. The only difference is the sheath tubing on the subject device is 11cm in length without a black marker tip and the sheath tubing on the predicate device is 4cm in length with a black marker tip.
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 Prelude® 7F Short 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* The following is a list of all significant testing that was successfully completed: • Dimensional verification • Force at break – junction between sheath introducer and sheath hub • Surface imperfections The results of the testing demonstrated that the subject Prelude® 7F Short Sheath Introducer met the pre-determined acceptance criteria applicable to the safety and efficacy of the device.
Summary of Substantial Equivalence	Based on the indications for use, design, safety and performance testing, the subject Prelude® 7F Short Sheath Introducer meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Prelude® Short Sheath Introducer, manufactured by Merit Medical Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Merit Medical Systems, Inc.
% Dan Clark
1600 West Merit Pkwy.
South Jordan, UT 84095 US

AUG 17 2012

Re: K122190
Trade/Device Name: Prelude 7F Short Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: July 23, 2012
Received: July 24, 2012

Dear Mr. Clark:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

Prelude® 7F Short Sheath Introducer
Section 4, Indications for Use
Special Premarket Notification 510(k)

Section 4

Indications for Use

510(k) Number (if known): K122190

Device Name: Prelude® 7F Short Sheath Introducer

Indications for Use:
The Prelude® 7F Short 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. This device can also provide access to a native or synthetic graft used for hemodialysis. The side port of the sheath allows adequate flow to perform temporary hemodialysis. The device is not indicated for long term vascular or hemodialysis access.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122190