OCT 15 2008

510(k) SUMMARY

GENERAL INFORMATION

Submitter Name:	Merit Medical Systems, Inc.
Address:	1600 Merit Parkway South Jordan, Utah 84095
Telephone Number:	801-208-4119 (direct)
Fax Number:	801-253-6918 (direct)
Contact Person:	Jerrie Hendrickson
Date of Preparation:	July 18, 2008

DEVICE INFORMATION

Trade or Proprietary Name:	Prelude® Short Sheath Introducer
Common or Usual Name:	Catheter Introducer
Product Code:	74 DYB
Classification Name:	Catheter Introducer (21 CFR 870.1340)
Classification Panel:	Cardiovascular

PREDICATE DEVICE(S)

- Hemodialysis Introducer Set (Distributed as DialEase™ Introducer Sheath), K961780

DEVICE DESCRIPTION

The Prelude® Short Sheath Introducer (*PSS*) consists of a sheath introducer with integral hemostasis valve. The side port extension tubing extending from the sheath hub may be used to infuse solutions and/or for temporary hemodialysis. A vessel dilator snaps securely into the sheath introducer hub. The *PSS* devices are available in 5 French (F) through 8F sizes in 4cm effective length. The vessel dilator is tipped specifically to accept either a 0.038" (0.97mm) or a 0.018" (0.46mm) diameter guide wire. The device is marketed with and without an appropriately sized guide wire and/or access needle.

INTENDED USE

Merit's *PSS* 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.

Traditional 510(k) Premarket Notification

510(k) Summary

TECHNOLOGICAL COMPARISON

Sheath introducers are manually operated devices that provide a percutaneous arterial or venous access route. Sheath introducers similar to the *PSS* devices employ the same fundamental technology, basic design and mode of operation.

The technological characteristics of the *PSS* device are substantially equivalent to those of the predicate device in terms of intended use, clinical utility and mode of operation, user population, basic design, materials, performance, labeling, packaging and sterilization method.

NON-CLINICAL PERFORMANCE TESTING

Verification and validation studies were conducted in accordance with in-house protocols to mitigate risks identified in the clinical risk assessment conducted by Merit. Performance testing was conducted or evaluated based on the following FDA Guidance and industry standards:

- ISO 11070: 1998: *Sterile, single-use intravascular catheter introducers*
- ISO 594-1: 1986: *Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 1: General Requirements*
- ISO 594-2: 1998: *Conical Fittings with 6% (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment – Part 2: Lock fittings*
- ISO 10993-1: 2003: *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing*
- FDA Bluebook memorandum G95-1: *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices, May, 1, 1995*
- ISO 10993-7: 1995: *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization residuals*
- ISO 11135: 1994: *Medical Devices – Validation and routine control of ethylene oxide sterilization*

Results of performance testing met the acceptance criteria and demonstrate substantial equivalence to the predicate devices.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Based on CDRH's substantial equivalence decision tree, the *PSS* is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

Merit Medical Systems, Inc.
c/o Mrs. Jerrie Hendrickson
Regulatory Affairs Specialist II
1600 West Merit Parkway
South Jordan, UT 84095

Re: K082063
Prelude Short Sheath Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: September 17, 2008
Received: September 19, 2008

Dear Ms. Hendrickson:

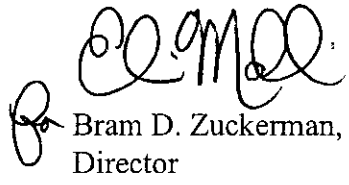
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K082063

Device Name: Prelude® Short Sheath Introducer

Indications for Use:

Merit's Prelude® 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__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K082063