SECTION 5: 510(k) SUMMARY

Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095

NOV 2 0 2007

K 073035

CONTACT: Shirley Hyink

DATE PREPARED: October 26, 2007

TRADE OR PROPRIETARY NAME: Prelude® Sheath Introducer

CLASSIFICATION NAME: Dilator, Vessel, For Percutanious Catheterization (870.1310)

PREDICATE DEVICES: Prelude® Sheath Introducer

DEVICE DESCRIPTION: Merit Medical System's *Prelude* Sheath Introducer consists of a sheath introducer with compatible vessel dilator that snaps securely into the sheath introducer hub. The sheath is equipped with a sideport attached to a segment of extension tubing terminating in a 3-way stopcock. The sheath hub contains an integral hemostasis valve and suture ring. The device is marketed with and without an appropriately sized guide wire and/or needle. The subject sheath introducers have a radiopaque marker tip.

INTENDED USE: The *Prelude* 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.

TECHNOLOGICAL COMPARISON : The modified device has the identical intended use and employs the same fundamental technology as the predicate device. A radiopaque marker tip is being added to the distal end of the sheath introducers.

PERFORMANCE TESTING: Verification and Validation Studies, conducted to demonstrate control of hazards identified in Merit's Clinical Risk Assessment, demonstrate that the modified devices met all of their pre-determined acceptance criteria and acceptably control the identified hazards.

SUMMARY OF SUBSTANTIAL EQUIVALENCE

Based on:

- Merit's conformance with Design Control requirements,
- Analyses of Risks associated with the Modified Device; and
- Results of Verification and Validation tests identified in the Clinical Risk Assessment, demonstrating that predetermined acceptance criteria have been met:

the modified devices are as safe and effective as, and perform as well as, or better than, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2007

Merit Medical System, Inc.
c/o Ms. Shirley Hyink
Manager, Regulatory Affairs
1600 West Merit Parkway
South Jordan, UT 84095

Re: K073035
Trade/Device Name: Prelude® Sheath Introducer
Regulation Number: 21 CFR 870.1310
Regulation Name: Dilator, Vessel for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: November 6, 2007
Received: November 7, 2007

Dear Ms. Hyink:

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) 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,

Donna R. Vochmes

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

Enclosure

SECTION 4: INDICATIONS FOR USE

510(k) Number (if known): K073035

Device Name: Prelude® Sheath Introducer

Indications for Use:

The Prelude® 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.

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)

Donna R Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K073035