K050962

MERIT MEDICAL

MAY - 6 2005

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Merit Medical Systems, Inc.
Merit Prelude™ Sheath Introducer
ABBREVIATED PREMARKET NOTIFICATION [510(k)]
CONFIDENTIAL
510(k) Summary (per 21 CFR 807.92)

11.0 Premarket Notification [510(k)] Summary of Safety and Effectiveness

Submitter	Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, Utah 84095-2416 USA
Establishment Registration Number	1721504
Contact Person(s)	
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Date Prepared	March 2, 2005

Merit Medical Systems, Inc.
Merit Prelude™ Sheath Introducer
ABBREVIATED PREMARKET NOTIFICATION [510(k)]
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510(k) Summary (per 21 CFR 807.92)

Name of Medical Device	Merit *Prelude* Sheath Introducer
Classification Name:	Vessel Dilator for Percutaneous Catheterization (21 CFR 870.1310)
Common/Usual Name:	Vessel Dilator/Introducer Sheath
Trade/Proprietary Name:	Merit *Prelude* Sheath Introducer

Device Classification

Panel:	Cardiovascular
Device Class:	Class II
Product Code:	74 DRE
Regulation Number:	21 CFR 870.1310

Predicate Device Identification

Device Brand Name	Cordis Avanti®+ Catheter Sheath Introducer System
Classification Name	Dilator, Vessel, For Percutaneous Catheterization
Device Class	Class II
Classification Panel Number	870 Cardiovascular Devices
Product Code	DRE
Clearance Status	K970392
Manufacturer	Cordis Corporation
Registration Number	1016427

Device Description

Merit's *Prelude* consists of a sheath introducer with side port extension and stopcock. The sheath hub includes a hemostasis valve and a suture ring. A 3-way stopcock is affixed to the proximal end of the side port extension. The *Prelude* assembly includes a vessel dilator that snaps securely into the sheath introducer hub.

Intended Use

The *Prelude* 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.

510(k) Summary (per 21 CFR 807.92)

Summary of Characteristics in Relation to Predicate Device

Does the new device have the same indication statement as the predicate device?
Yes.
Although there are minor differences, the intended use is the same, (i.e., to gain intravascular access).

Does the new device have the same technological characteristics, e.g., design, materials, etc. as the predicate device?
Yes.
The Merit *Prelude* Sheath Introducer employs a similar method of operation and design as compared to the predicate device. Both devices consist of a sheath introducer that has a side port extension tube with a stopcock attached to it and a vessel dilator. Both devices are comprised of similar materials and are the same sizes.

Are the descriptive characteristics precise enough to ensure equivalence to the predicate device?
No.
Bench testing was conducted on the *Prelude* in order to establish substantial equivalence. Comparative testing with the predicate device performed includes radiodetectability of the sheath introducer and vessel dilator, valve leak pressure, tip insertion force, sheath hub/cap snap fit, dilator snap fit to sheath hub, and guide wire compatibility.

Are performance data available to assess effects of the new device as compared to the predicate device?
Yes.
Performance testing was conducted according to international standards as well as Merit's in-house protocols. Where performance could affect the safety or effectiveness of the *Prelude*, comparison with the predicate device was conducted (i.e., valve leak, tip insertion force).

Does performance data demonstrate equivalence?
Yes.
Performance data demonstrate that the *Prelude* is substantially equivalent to the predicate device.

Conclusion: "Substantial Equivalence" Determination
Based on CDRH's substantial equivalence decision tree, the *Prelude* 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

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Kema Quality B.V.
c/o Ms. Jerry Hendrickson
Regulatory Affairs Specialist
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, Utah 84095-2416

Re: K050962
Trade Name: Merit Prelude™ Sheath Introducer
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: II
Product Code: DRE
Dated: April 15, 2005
Received: April 18, 2005

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 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

Merit Medical Systems, Inc.
Merit Prelude™ Sheath Introducer
ABBREVIATED PREMARKET NOTIFICATION [510(k)]
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INDICATION(S) FOR USE STATEMENT *

510(k) Number (if known): K050962

Device Name: Merit Prelude™ Sheath Introducer

Indications for Use:

The Merit 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___ (Part 21 CFR 901 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart O)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vechinski
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050962