K082644

SEP 18 2008

SECTION II. 510(K) SUMMARY

A. Device Name

Proprietary Name	Glidesheath
Classification Name	Introducer, Catheter
Common Name	Introducer Sheath

B. Intended Use

The Glidesheath is used to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.

The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery including but not limited to the radial artery.

The Radifocus Obturator is also an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling sheath while it remains in place within the vein or artery, including but not limited to the radial artery, after removal of a catheter.

C. Device Description

The Glidesheath is comprised of an introducer sheath and a dilator. The Glidesheath is coated with a hydrophilic coating to reduce the frictional resistance of the sheath when inserting or removing the sheath from the patient's blood vessel. The Glidesheath is used to facilitate placing a catheter through the skin into a vein or artery including but not limited to the radial artery.

The Mini Guide Wire is an accessory device which is used for placement of the sheath into the vein or artery including but not limited to the radial artery. The Mini Guide Wire is inserted through a cannula placed in the patient's blood vessel. The Glidesheath is then inserted over the Mini Guide Wire and into the blood vessel. The Mini Guide Wire is then withdrawn from the vessel. The Dilator maintains the integrity of the Sheath and dilates the blood vessel while the Glidesheath is being placed into the vessel. The Dilator can be removed and an appropriate catheter can then be inserted.

The Obturator is also an accessory device which is used by placing it into the sheath to create an occlusion and further provide support to the wall of the indwelling sheath while it remains in place within the vein or artery, including but not limited to the radial artery, after removal of a catheter. The Obturator is sold separately.

The Sheath, Dilator and Obturator contain bismuth, making these devices visible under fluoroscopy.

Accessories to the Glidesheath are the mini guide wire, Surflo IV catheter, Syringe, and Scalpel, and the RADIFOCUS Obturator. Depending on the product code, these accessories may or may not be contained within the kit. All of the accessories are packaged with the Glidesheath in a pouch prior to sterilization.

D. Principle Of Operation / Technology

The Glidesheath and its accessories are operated manually or by a manual process.

E. Design / Materials

Differences in materials between the modified device and the predicate device the Glidesheath cleared under K062858 and the Cordis Avanti™ cleared under K962746 raise no new issues of safety and effectiveness.

F. Specifications

Sheath Sizes:	4, 5 & 6 French
Sheath Length:	10-25 cm
Dilator Length:	15.5 – 30.5 cm
Guide Wire OD:	0.021" – 0.038" 10 – 180cm
Surflo IV Catheter:	16G-22G 1" – 2.5" length
Hydrophilic Coating:	10-25cm (entire length of Sheath)

G. Performance

A risk/hazard analysis was conducted according to EN ISO 14971 Medical Devices – Application of risk management to medical devices. Performance characteristics for this new indication for use were determined. Then it was justified that the performance of the Glidesheath is substantially equivalent to the performance of the Glidesheath cleared under K062858 and the Cordis Avanti™ cleared under K962746.

H. Additional Safety Information

Manufacturing controls include visual, functional, dimensional and sterility tests.

Blood contacting materials were tested in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing".

The introducer sheath is classified as Externally Communicating Devices, Circulating Blood, Prolonged Contact (24 hrs to 30 days). Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance with EN ISO 11135-1, Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of sterilization process for medical devices. The device is sterilized to a SAL of 10^{-6}.

H. Substantial Equivalence

The Glidesheath is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate device the Glidesheath, cleared under K062858 and the Cordis Avanti™ cleared under K962746. Differences between the devices do not raise any significant issues of safety or effectiveness.

I. Submitter Information

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Date Prepared: August 21, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 18 2008

Terumo Corporation
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K082644
Glidesheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 10, 2008
Received: September 11, 2008

Dear Mr. Job:

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,

Donna R. Vichman

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

Enclosure

Indications for Use

510(k) Number (if known): K082644

Device Name: Glidesheath™

Indications For Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

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