MAY 28 2008

SECTION II. 510(k) SUMMARY

A. DEVICE NAME

Proprietary Name:	Destination® Renal Guiding Sheath
Classification Name:	Catheter Introducer
Common Name:	Guiding Sheath

B. PREDICATE DEVICE

The predicate device is the Renal Guiding Sheath, which is manufactured by Terumo Medical Corporation. The Renal Guiding Sheath is cleared through the premarket notification process (K012854).

C. INTENDED USE

The Destination® Renal Guiding Sheath is intended for the introduction of interventional and diagnostic devices into the human vasculature including but not limited to the Renal Arteries.

D. DESCRIPTION

The Destination® Renal Guiding Sheath is designed to perform as a guiding catheter and an introducer sheath. The Guiding Sheath is packaged with the following components: a Sheath, a Dilator, a Hemostatic Valve, and a Dilator Retaining Clip.

E. PRINCIPLE OF OPERATION / TECHNOLOGY

The Destination® Renal Guiding Sheath is operated manually or by a manual process.

F. DESIGN / MATERIALS

The Destination® Renal Guiding Sheath uses similar materials as the predicate device. Differences in materials between the two devices do not raise any new issues of safety and effectiveness.

G. SPECIFICATIONS

Sheath Size:	5Fr.
Sheath Length:	45-55 cm
Hydrophilic Coating:	Distal 5 cm
Distal Shape Configurations:	Straight, HS, RDC, LIMA, MP

H. PERFORMANCE

The performance of the Destination® Renal Guiding Sheath is substantially equivalent to the performance of the unmodified Renal Guiding Sheath. The equivalence was shown through bench and vessel model testing.

I. ADDITIONAL SAFETY INFORMATION

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." to provide a Sterility Assurance Level of 10^{-6}.

Blood contacting materials were tested in accordance with the test recommendations in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part I: Evaluation and Testing." The Destination® Renal Guiding Sheath is categorized as "Externally Communicating Device, Circulating Blood, Limited Contact (≤24hrs)". The blood contacting materials were found to be biocompatible.

Expiration dating for the Destination® Renal Guiding Sheath will be 30 months.

J. SUBSTANTIAL EQUIVALENCE

The Destination® Renal Guiding Sheath submitted in this 510(k) is substantially equivalent in intended use, design, principle of operation / technology, materials and performance to the Renal Guiding Sheath (K012854), which is manufactured by Terumo Medical Corporation. Differences between the devices do not raise any issues of safety or effectiveness.

K. SUBMITTER INFORMATION

Name and Address

Terumo Medical Corporation
950 Elkton Blvd.
Elkton, MD 21921

Contact Person

Mr. Mark Unterreiner
Sr. Regulatory Affairs Specialist
Ph: 410-392-7213
Fax: 410-398-6079
Email: mark.unterreiner@terumomedical.com

Date Prepared

April 11, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 28 2008

Terumo Medical Corporation
c/o Mr. Mark Unterreiner
Sr. Regulatory Affairs Specialist
950 Elkton Blvd.
Elkton, MD 21921

Re: K081045
Trade/Device Name: Destination Renal Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: DYB
Dated: May 19, 2008
Received: May 20, 2008

Dear Mr. Unterreiner:

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 Biometric's (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. Vuckner

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

Indications for Use

510(k) Number (if known): K081045

Device Name: Destination® Renal Guiding Sheath

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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. Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K081045