K012854

NOV 21 2001

SECTION II. SUMMARY OF SAFETY & EFFECTIVENESS

A. DEVICE NAME

Proprietary Name:	Has not been established yet
Classification Name:	Catheter Introducer
Common Name:	Guiding Sheath

B. PREDICATE DEVICE

The predicate device is the *Super Arrow-Flex Percutaneous Sheath Introducer Set*, which is manufactured by Arrow International, Inc. The Super Arrow-flex is cleared through the premarket notification process (K924607).

C. INTENDED USE

The 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 Renal Guiding Sheath is designed to perform as a guiding catheter and an introducer sheath. The sheath is coil reinforced, has a radiopaque marker and is hydrophilically coated on the distal 5 cm. It comes packaged with a dilator, a rotating hemostatic valve (or a detachable hemostatic valve), and a dilator retaining clip.

E. PRINCIPLE OF OPERATION / TECHNOLOGY

The Renal Guiding Sheath and the Super Arrow-Flex Percutaneous Sheath Introducer Set are operated manually or by a manual process.

F. DESIGN / MATERIALS

The Renal Guiding Sheath use 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:	6-7Fr.
Nominal ID / OD:	6Fr.: .087" / .109"
	7Fr.: .100" / .122"
Sheath Length:	45-55cm
Hydrophilic Coating:	Distal 5 cm
Distal Shape Configurations:	Straight, Hockey Stick, Multipurpose

H. PERFORMANCE

The performance of the Renal Guiding Sheath is substantially equivalent to the performance of the Super Arrow-Flex Percutaneous Sheath Introducer. The following tests were performed to demonstrate the substantial equivalence of the devices.

- Penetration
- Kink Resistance
- Leakage
- Tensile Strength
- Tortuous Path / Durability

I. ADDITIONAL SAFETY INFORMATION

Sterilization conditions have been validated in accordance with ANSI / AAMI / ISO 11135-1994 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 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 Renal Guiding Sheath will be 30 months.

J. SUBSTANTIAL EQUIVALENCE

The Renal Guiding Sheath submitted in this 510(k) is substantially equivalent in intended use, design, principle of operation / technology, materials and performance to the *Super Arrow-Flex Percutaneous Sheath Introducer Set (K924607)*, which is manufactured by Arrow International, Inc. Differences between the devices do not raise any issues of safety or effectiveness.

Terumo's statement of substantial equivalence is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended whatsoever to be the basis for a patent infringement action.

K. SUBMITTER INFORMATION

Name and Address

Terumo Medical Corporation
125 Blue Ball Rd.
Elkton, MD 21921

Contact Person

Mrs. Yuk-Ting Lewis
Senior Regulatory Specialist
Ph: 410-392-7213
Fax: 410-398-6079
Email: yukting.lewis@terumomedical.com

Date Prepared

August 1, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2001

Ms. Yuk-Ting Lewis
Senior Regulatory Specialist
TERUMO Medical Corporation
125 Blue Ball Road
Elkton, MD 21921

Re: K012854
Renal Guiding Sheath
Regulation Number: 870.1340
Regulation Name: Catheter introducer.
Regulatory Class: II (two)
Product Code: 74 DYB
Dated: August 23, 2001
Received: August 24, 2001

Dear Ms. Lewis:

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.

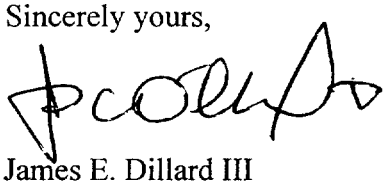
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012854

Device Name: Renal Guiding Sheath

Indications For Use:

The 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012854