JUN 29 2006

SECTION V. 510(k) SUMMARY

A. DEVICE NAME

Proprietary Name:	Carotid Access Kit
Classification Name:	Percutaneous Catheter
Common Name:	Guide Wire, Catheter, and Introducer

B. PREDICATE DEVICE

The predicate device are:

Product Name: Terumo Radifocus® Guide Wire
510k #: K863138
Manufacaturer: Terumo Corporation

Product Name: Terumo Angiographic Catheter
510k #: K915414
Manufacaturer: Terumo Corporation

Product Name: Pinnacle Destination Carotid Guiding Sheath
510k #: K012812
Manufacaturer: Terumo Medical Corporation

C. INDICATIONS FOR USE

The Glidewire® guide wire is designed to direct a catheter to the desired anatomical location, including but not limited to the carotid arteries, during diagnostic or interventional procedures.

The GlideCath® XP catheter is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system, including but not limited to the carotid arteries.

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

D. DESCRIPTION

The Carotid Access Kit is designed to be used for the introduction of devices during carotid intravascular procedures. The kit consists of a Glidewire® guide wire, GlideCath® XP catheter, Tuohy-Borst Valve (TBV), Destination® Carotid Guiding Sheath and inner sheath. The inner sheath is composed of PTFE and the distal end is tapered to provide a smooth transition from the GlideCath XP to the Destination Carotid Guiding Sheath. All components are STERILE. They are sterilized using Ethylene Oxide (EtO) gas.

E. PRINCIPLE OF OPERATION / TECHNOLOGY

The devices in the Carotid Access Kit are operated manually or by a manual process.

F. DESIGN / MATERIALS

The Carotid Access Kit uses similar materials as the predicate device. Differences in materials between the devices do not raise any new issues of safety and effectiveness.

G. SPECIFICATIONS

Glidewire Specifications: 180 to 300 cm length
GlideCath XP Specifications: 180 to 300 cm length with H1 and Vitek shaped distal end
Destination Carotid Guiding Sheath Specifications: 6 & 7Fr, 90 cm length, Straight and Multipurpose shaped distal end, with Tuohy-Borst Valve and Inner sheath

H. PERFORMANCE

The performance of the Carotid Access Kit is substantially equivalent to the performance of the predicate devices. The equivalence was shown through bench testing.

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 Carotid Access Kit is categorized as "Externally Communicating Device, Circulating Blood, Limited Contact (≤24hrs)". The blood contacting materials were found to be biocompatible.

Expiration dating for the Carotid Access Kit will be dependent on the selflife remaining on the kit components. The maximum shelflife for the kit is 24 months.

J. SUBSTANTIAL EQUIVALENCE

The Carotid Access kit submitted in this 510(k) is substantially equivalent in intended use, design, principle of operation / technology, materials and performance to the predicate devices, which are manufactured by Terumo Medical Corporation and Terumo 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

March 13, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2006

Terumo Medical Corporation
c/o Mr. Mark Unterreiner
Sr. Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K060666
Carotid Access Kit
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DYB
Dated: May 31, 2006
Received: June 1, 2006

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 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Volkmer

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): K060666

Device Name: Carotid Access Kit

Indications For Use:

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

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. Mc Nally

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K060666