K063372

SECTION II. 510(K) SUMMARY

A. Device Name

JAN 19 2007

Proprietary Name	Radifocus® Glidewire® Advantage
Classification Name	Wire, Guide, Catheter
Common Name	Guide Wire

B. Intended Use

The Radifocus® Glidewire® Advantage is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.

Note: This is the same intended use as the predicate device – Radifocus Guide Wire K863138

C. Device Description

The Radifocus Glidewire Advantage consists of a Nickel Titanium alloy core wire. A polyurethane and hydrophilic coating is applied to the distal portion of the wire while a PTFE coating is applied to the proximal portion. The wire distal segment comes in many configurations such as straight, J shaped, and angled. The wire is package in a plastic holder contained within a pouch. A guide wire inserter is contained within the pouch to assist with the insertion of the wire into a needle or catheter.

D. Principle Of Operation / Technology

The Radifocus Glidewire Advantage is operated manually or by a manual process.

E. Design / Materials

Differences in materials between the modified device and the predicate device the Radifocus Guide Wire cleared under K863138 raise no new issues of safety and effectiveness.

F. Specifications

Part	Modified Radifocus® Glidewire® Advantage	Radifocus® Guide Wire cleared under K863138
Diameter of Wire	0.018"- 0.038"	0.018" – 0.038"
Length of Wire	150-300 cm	30-300 cm
Shapes of Wire	Angled, straight, J shaped	Angled, straight, J shaped
Accessory Devices	Guide wire inserter	Guide wire inserter

G. Performance

The following verification tests were performed to demonstrate the substantial equivalence of the modified device (Radifocus Glidewire Advantage) to the unmodified device (Radifocus Guide Wire).

- Ease of removal from holder
- Torque control
- Sliding friction
- Tip impact
- Proximal shaft stiffness
- Bend strength

None of the data raises any new issues of safety and effectiveness. Additionally, a risk analysis was conducted and there were no new issues of safety and effectiveness.

Therefore the performance of the modified Radifocus Glidewire Advantage is substantially equivalent to the performance of the predicate device the Radifocus Guide Wire which was cleared under K863138.

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 guide wire is classified as Externally Communicating Devices, Circulating Blood, Limited Contact ($\leq$ 24 hrs). Results of the testing demonstrate that the blood contacting materials are biocompatible.

Sterilization conditions have been validated in accordance with ANSI / AAMI / ISO 11135-1994, *Medical Devices – Validation and routine control of ethylene oxide sterilization* and EN 550. The device is sterilized to a SAL of 10^{-6}.

H. Substantial Equivalence

The modified Radifocus Glidewire Advantage is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate device the Radifocus Guide Wire, cleared under K863138. Differences between the two devices do not raise any significant issues of safety or effectiveness.

I. Submitter Information

Prepared By:	Mr. Mark Unterreiner Sr. Regulatory Affairs Specialist
Prepared For:	Terumo Medical Corporation 950 Elkton Blvd. Elkton, MD 21921 Phone: (410) 392-7213 Fax: (410) 398-6079 Email: mark.unterreiner@terumomedical.com
Date Prepared:	November 8, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

JAN 19 2007

Re: K063372
Radifocus® Guidewire® Advantage
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: II (two)
Product Code: DQX
Dated: December 20, 2006
Received: December 21, 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,

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): K063372

Device Name: Radifocus® Glidewire® Advantage

Indications For Use:

The Radifocus® Glidewire® Advantage is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.

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)

Shannon R. Mumma
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063372