K090040

FEB - 6 2009

SECTION II. 510(K) SUMMARY

A. Device Name

Proprietary Name:	RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP)
Classification Name:	Diagnostic Intravascular Catheter
Common Name:	Angiographic Catheter

B. Intended Use

The RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP) is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guide wire or a catheter into the target site.

C. Device Description

The RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP) is a two-layer construction comprised of a stainless steel mesh sandwiched between layers of polyurethane polyamide elastomer. The polyurethane polyamide elastomer contains barium sulfate for visibility and contrast under fluoroscopy. There is a hydrophilic coating on the distal portion of the device. The length of the coating is determined by the product code number.

D. Principle of Operation / Technology

The RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP) is operated manually or by a manual process.

E. Design / Materials

The RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP) in this submission is the same device that was cleared under K915414, the Terumo Angiographic Catheter. There are no changes in the design or materials.

F. Specifications

Available Sizes	4 & 5 Fr.
Catheter Length	30 – 150 cm
Maximum Injection Pressure	4 Fr.: 750 psi 5 Fr.: 1000 psi

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 RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP) is substantially equivalent to the performance of the Terumo Angiographic Catheter cleared under K915414.

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 catheter 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 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 RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP) is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate device the Terumo Angiographic Catheter, cleared under K915414. Differences between the devices do not raise any significant issues of safety or effectiveness.

I. Submitter Information

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Date Prepared: December 22, 2008

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 6 2009

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

Re: K090040
Trade/Device Name: RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP)
Common Name: Diagnostic intravascular catheter
Regulation Number: 21 CFR 870.1200
Regulatory Class: II
Product Code: DQO
Dated: January 23, 2008
Received: January 26, 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) 276-0210. 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,

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): K090040

Device Name: RADIFOCUS® Glidecath® (or RADIFOCUS Glidecath XP)

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090040