MAR 0 1 2013

510(k) Summary

Radifocus® Glidewire Advantage (0.014")

January 24, 2013

A. *General Information*

Applicant: Terumo Corporation, Tokyo, Japan
44-1, 2-chome Hatagaya
Shibuya-ku Tokyo
151-0072 Japan
Registration No: 801 002 6

Official Correspondent: Stacy Abbatiello Kluesner, M.S., RAC
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Terumo Medical Corporation
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B. *Device Name*

Proprietary Name:	Radifocus® Glidewire Advantage (0.014")
Classification Name:	Wire, Guide, Catheter
Common Name:	Guide Wire
Regulation Number:	21 CFR 870.1330
Regulatory Description:	Catheter guide wire
Regulatory Class:	II
Review Panel:	Cardiovascular
Product Code:	DQX

C. *Intended Use*

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

D. Predicate Device

Terumo Corporation, Radifocus® Glidewire Advantage (K063372)

E. Device Description

The Radifocus® Glidewire Advantage (0.014") 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 an angled configuration. The Radifocus® Glidewire Advantage (0.014") diameter wire contains a distal radiopaque spring coil. The wire is package in a plastic holder contained within an individual package. A guide wire inserter is contained within the individual package to assist with the insertion of the wire into a needle or catheter.

F. Technological Comparison

The Radifocus® Glidewire Advantage (0.014") is identical to the predicate device in intended use, and is similar in the design specifications. The main difference between the subject device and the predict device is in the wire diameter offered.

Part	Modified Radifocus® Glidewire Advantage (0.014")	Predicate Radifocus® Glidewire Advantage (K063372)
Diameter of Wire	0.014"	0.018" – 0.038"
Length of Wire	180, 300 cm	150-300 cm
Shapes of Wire	Angled	Angled, straight, J shaped
Accessory	Guide wire inserter	Guide wire inserter

G. *Performance Testing*

The following bench tests were performed to verify that the subject device is substantially equivalent to the predicate device and that there are no new issues regarding the safety and effectiveness of the device:

Performance Testing for the Radifocus® Glidewire Advantage	
Verification Test	Test Method
Torque control	Test method developed in-house
Sliding Friction (hydrophilic coating)	Test method developed in-house
Sliding Friction (PTFE coating)	Test method developed in-house
Pushing Resistance at Tip (Tip impact)	Test method developed in-house
Proximal Shaft Stiffness	Test method developed in-house
Bend Strength	Test method developed in-house
Tensile Strength	Coronary and Cerebrovascular Guidewire Guidance – January 1995
Torque Strength	Coronary and Cerebrovascular Guidewire Guidance – January 1995
Coating Adherence/Integrity	Coronary and Cerebrovascular Guidewire Guidance – January 1995
Particulate Test	Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PCTA) Catheters

H. *Additional Safety Information*

As the device incorporated materials that had not been previously used together on this device, biocompatibility testing was performed to ensure the material safety in accordance with the tests recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1. "Biological Evaluation of Medical Devices Part-1: Evaluation and testing within a risk management process." The Radifocus® Glidewire Advantage is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24h). The specific tests performed and passed were as follows:

Biocompatibility Testing for the Radiofocus® Glidewire Advantage		
Test	Test Method	Result
Cytotoxicity	ISO 10993-5	Non-cytotoxic
Hemolysis	ASTM F756-08	Non-hemolytic.
Thromboresistance	ISO10993-4	Thromboresistant
Sensitization	ISO 10993-10	No evidence of causing delayed dermal contact sensitization.
Acute Systemic Toxicity	ISO 10993-11	No mortality or evidence of systemic toxicity.
Intracutaneous Reactivity	ISO 10993-10	No evidence of significant irritation or toxicity.
Pyrogen	ISO 10993-11	Non-pyrogenic.
Complement Activation Testing C3a	ISO 10993-4	Not a complement system activator
Complement Activation Testing Sc5b-9	ISO 10993-4	Not a complement system activator
Physicochemical Profile	USP35<661>	Meets requirements

Risk Analysis was performed in accordance with established in-house acceptance criteria based on ISO 14971. The design verification tests and their acceptance criteria were identified and performed as a result of this risk analysis assessment.

Sterilization conditions have been validated in accordance with ANSI/AAMI/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}.

I. Substantial Equivalence

When compared to the predicate device, the modified Radifocus® Glidewire Advantage (0.014") is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate Radifocus® Glidewire Advantage device cleared under K063372. Differences between the two devices do not raise any new concerns regarding the safety and effectiveness of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Terumo Medical Corporation
c/o Ms. Stacy Kluesner
265 Davidson Ave, Suite 320
Somerset, New Jersey 08873

Re: K122590
Trade/Device Name: Radifocus Guidewire Advantage
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: January 30, 2013
Received: February 1, 2013

Dear Ms. Kluesner:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G Hillebrenner

for 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): K122590

Device Name: Radifocus® Glidewire Advantage

Indications For Use:

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Matthew G. Hillebrenner