K063695

SECTION II. 510(K) SUMMARY

APR 27 2007

A. *Device Name*

Proprietary Name	Runthrough NS
Classification Name	Wire, Guide, Catheter
Common Name	Guide Wire

B. *Intended Use*

The Runthrouh NS are used to facilitate placement of balloon dilatation catheters for percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

Note: This is the same intended use as the predicate device – Radifocus® Glidewire for Coronary Use with Platinum or Gold Coil, K961445.

C. *Device Description*

The Runthrough NS is a coil-type guide wire. The main components of the wire include a core wire, a tip coil, a tip coil marker, and surface coating. The core wire is constructed of a Ni/Ti alloy wire and a stainless steel wire joined together. The tip coil marker, a Pt/Ni alloy, is radiopaque. The tip coil has lubricous coating (silicone coating) and/or hydrophilic coating on the surface depending on product code. The shaft is surface-coated with silicone and PTFE. Tip flexibility can be selected among three types, Extra Floppy, Floppy, and Intermediate, flexibility decreasing in the named order. The wire is also available in a hyper-coating type which is more lubricous than the standard wire. The device may be accompanied by a torque device, inserter, and stylet accessories.

D. *Principle Of Operation / Technology*

The Runthrough NS is operated manually or by a manual process.

E. Design / Materials

Differences in materials between the modified device and the predicate device the Radifocus® Glidewire for Coronary Use with Platinum or Gold Coil cleared under K961445 raise no new issues of safety and effectiveness.

F. Specifications

Feature	Modified Runthrough NS	Unmodified Device Radifocus® Glidewire for Coronary Use with Platinum or Gold Coil cleared under K961445
Available diameter	0.014" (0.36mm)	0.014" (0.36mm)
Available length	180cm, 300cm	180cm, 300cm
Tip marker length	30mm	20mm
Accessory Devices	Torque Device, Inserter, Stylet	Torque Device, Inserter
Shelf life	36 months	24 months

G. Performance

The following verification tests were performed to demonstrate the substantial equivalence of the modified device (Runthrough NS) to the unmodified device (Radifocus® Glidewire for Coronary Use with Platinum or Gold Coil, K961445).

- Dimensional Inspection
- Tip sliding resistance test
- Tensile strength of tip
- Tip butting load
- Tensile strength of shaft
- Wire stability in holder loop
- Bend strength
- Seal strength of packaging
- Reshapability
- Torque Strength
- Torqueability
- Tip Flexibility
- Coating Adherence/Integrity

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 Runthrough NS is substantially equivalent to the performance of the predicate device the Radifocus® Glidewire for Coronary Use with Platinum or Gold Coil, K961445.

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 Runthrough NS is substantially equivalent in intended use, design, technology/principles of operation, materials and performance to the predicate device the Radifocus® Glidewire for Coronary Use with Platinum or Gold Coil, K961445. Differences between the two devices do not raise any significant issues of safety or effectiveness.

I. Submitter Information

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Date Prepared: December 12, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 2007

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

Re: K063695
Runthrough NS
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter guidewire
Regulatory Class: II (two)
Product Code: DQX
Dated: April 4, 2007
Received: April 5, 2007

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. Volchmer

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): K063695

Device Name: Runthrough NS

Indications For Use:

The Runthrouh NS are used to facilitate placement of balloon dilatation catheters for percutaneous transluminal coronary angioplasty (PTCA) and/or percutaneous transluminal angioplasty (PTA).

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)

Donna R. Vechinski

(Division Sign-Off)
Division of Cardiovascular Device

510(k) Number K063695