DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 30, 2017

Terumo Medical Corporation
Mr. Liang Lu
Senior Regulatory Affairs Specialist
950 Elkton Blvd.
Elkton, MD 21921

Re: K163004
Trade/Device Name: Radifocus Glidewire Advantage Track
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: October 25, 2016
Received: November 2, 2016

Dear Mr. Lu:

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.

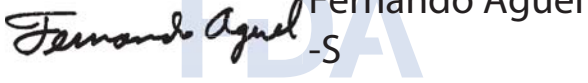
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163004

Device Name
Radifocus Glidewire Advantage Track

Indications for Use *(Describe)*
The Radifocus Glidewire Advantage Track is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary interventions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

A. SUBMITTER INFORMATION (807.92(a)(1))

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Prepared for: ***Owner/Operator***
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Date prepared: January 23, 2016

B. DEVICE NAME (807.92(a)(2))

Proprietary Name:	Radifocus Glidewire Advantage Track
Common Name:	Guide Wire
Classification Name:	Wire, Guide, Catheter
Classification Panel:	Cardiovascular
Regulation:	21CFR870.1330
Product Code:	DQX
Classification:	Class II

C. PREDICATE DEVICE (807.92(a)(3))

The legally marketed device(s) to which substantial equivalence is claimed are:

- K122590 and K063372 - Radifocus Glidewire Advantage manufactured by Ashitaka Factory of Terumo Corporation.

The following competitors' devices were used as reference devices:

510(K) No.	Competitor's product	Competitor's name
K033742	V-18	Boston Scientific
K112745	V-14	Boston Scientific
K052339	Miracle	ASAHI INTECC
K122573	Command	Abbott Vascular
K152709	Spartacore	Abbott Vascular

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the Radifocus Glidewire Advantage Track, manufactured by Ashitaka Factory of Terumo Corporation, for the modifications on the previously cleared predicate device (K122590 and K063372) manufactured by the same factory.

The proposed Radifocus Glidewire Advantage Track is identical to the predicate Radifocus Glidewire Advantage (K122590 and K063372) with the exception of the following:

- The proximal core wire material of the predicate device (K063372 and K122590 Radifocus Glidewire Advantage) is being modified from NiTi (Nickel Titanium alloy) to Stainless Steel;

- The angle of the angle-shape wire distal tip is being modified from 45° to 35°;
- The labeling for the proposed Radifocus Glidewire Advantage Track is being slightly modified

E. DEVICE DESCRIPTION (807.92(a)(4))

Principle of Operation Technology

The Radifocus Glidewire Advantage Track is operated by manual process.

Design/Construction

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

The Radifocus Glidewire Advantage Track consists of a Nickel Titanium alloy and stainless steel core wire. The distal portion from the junction is NiTi and the proximal portion is stainless steel. 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 angled configuration. The wire contains a distal radiopaque gold coil. The wire comes packaged 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.

During an interventional or diagnostic procedure, the physician will follow the standard procedure of placing an access wire and introducer within a vessel. Once the introducer is placed, the physician may choose a wire such as the Radifocus Glidewire Advantage Track to gain access to the target lesion or therapeutic site. It is also used in conjunction with a catheter which is advanced over the wire to the desired anatomical location.

Materials

The materials for the Radifocus Glidewire Advantage Track are provided in **Table 1** below.

Table 1: List of Materials

Part		Raw material
Core wire*(Proximal portion from junction)		Stainless steel
Core wire*(Distal portion from junction)		Nickel-Titanium alloy
First coating*		Polyurethane containing tungsten
Second coating on distal portion of wire* (Hydrophilic polymer)		-Hydrophilic polymer Half-ester methyl vinyl ether-maleic anhydridecopolymer -Under coat Polyvinyl chloride
PTFE spiral coating on proximal portion of wire	Under coating	Polytetrafluoroethylene (PTFE)
	Top coating*	
	Spiral coating*	
Edge protection part	Metal part*	Platinum/ Iridium (Pt/Ir)
	Solder*	Tin/Silver (Sn/Ag)
Third coating on edge protection part* (Hydrophilic polymer)		Dimethyle acrylamideglycidyl methacrylate copolymer
Tip coil marker		Gold (Au)

* Blood contacting material

Specifications

The specifications for the Radifocus Glidewire Advantage Track are provided in the **Table 2** below.

Table 2: Radifocus Glidewire Advantage Track Specifications

Part	Specification
Diameter of Wire	0.014 and 0.018”
Length of Wire	180 and 300 cm*
Shapes of Wire (distal tip)	Angled (Tip angle 35°)

* tolerance: ± 20 mm

F. INDICATIONS FOR USE (807.92(a)(5))

The Radifocus Glidewire Advantage Track is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary interventions.

Note: The indications for use are identical to the predicate device, Radifocus Glidewire Advantage (K122590 and K063372).

G. SUBSTANTIAL EQUIVALENCE COMPARISON (807.92(a)(6))

The Radifocus Glidewire Advantage Track, subject of this traditional 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to:

- Predicate Device: K063372 and K122590 – Radifocus Glidewire Advantage, manufactured by Ashitaka Factory of Terumo Corporation.

A comparison of the technological characteristics is summarized in **Table 3** below.

Table 3: Comparison of Device Characteristics	**New Device: Radifocus Glidewire Advantage Track**	**Predicate Device: Radifocus Glidewire Advantage (K063372)**	**Predicate Device: Radifocus Glidewire Advantage (K122590)**
Manufacturer	Ashitaka Factory of Terumo Corp.	Same	Same
Intended Use/Indication for Use	Designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. This device is not intended for neurovascular or coronary interventions.	Same	Same
Operation Principle	Manual	Same	Same
Design/ Construction	The Radifocus Glidewire Advantage Track consists of a Nickel Titanium alloy (distal) and stainless steel (proximal) 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 angled configuration. The wire contains a distal radiopaque gold coil. The wire is packed 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.	The Radifocus Glidewire Advantage consists of a Nickel Titanium alloy core wire Same (the distal radiopaque gold coil is for the 0.018" only). Same	The Radifocus Glidewire Advantage consists of a Nickel Titanium alloy core wire. Same Same

Materials	• Core wire o (Proximal portion from junction): Stainless steel o (Distal portion from junction): Nickel-Titanium alloy • First coating: Polyurethane containing tungsten • Second coating on distal portion of wire o (Hydrophilic polymer): Half-ester methyl vinyl ether-maleic anhydridecopolymer o Under coat: Polyvinyl chloride • PTFE spiral coating on proximal portion of wire: o Polytetrafluoroethylene (PTFE) • Edge protection part o Metal part: Platinum/ Iridium (Pt/Ir) o Solder: Tin/Silver (Sn/Ag) • Third coating on edge protection part o (Hydrophilic polymer): Dimethyle acrylamideglycidyl methacrylate copolymer • Tip coil marker: Gold (Au) available for 0.014” and 0.018”	Same unless mentioned below: • Core wire: Nickel-Titanium alloy • First coating: Polyurethane containing tungsten • Tip coil marker: Gold (Au) only available for 0.018”	Same as K063372 unless mentioned below: • Tip coil marker: Gold (Au) only available for 0.014”

Package	• Individual package on which the product label and the peel-off labels are attached • 1 unit per package	Same	Same
Specifications	• Diameter of Wire: 0.014 and 0.018” • Length of Wire: 180 and 300 cm * tolerance: ± 20 mm • Shapes of Wire (distal tip): Angled (Tip angle 35°) • Accessory Devices: Guide wire inserter	• Diameter of Wire: 0.018 - 0.038” • Length of Wire: 150 - 300 cm * tolerance: ± 20 mm • Shapes of Wire (distal tip): Angled (Tip angle 45°), straight, J shaped • Accessory Devices: Guide wire inserter	• Diameter of Wire: 0.014” • Length of Wire: 180 and 300 cm * tolerance: ± 20 mm • Shapes of Wire (distal tip): Angled (Tip angle 45°) • Accessory Devices: Guide wire inserter
Sterilization	Ethylene oxide	Same	Same
Shelf Life	24 months	Same	Same

H. NON CLINICAL TESTS (807.92(b)(1))

Performance Testing

Performance testing was conducted to demonstrate substantial equivalence to the predicate device, to verify conformity to applicable external and internal standards, and verify that aging does not affect the Radifocus Glidewire Advantage Track. All testing met acceptance criteria. **Table 4** below provides a list of the performance tests that were performed on the proposed Radifocus Glidewire Advantage Track.

Table 4: Summary of Performance Testing

Test	Standard
Surface	ISO 11070: 2014 Section 4.3
Corrosion resistance	ISO 11070: 2014 Section 4.4
Radio-detectability	ISO 11070: 2014 Section 4.5
Size designation	ISO 11070: 2014 Section 8.2
Fracture test	ISO 11070: 2014 Section 8.4
Flexing test	ISO 11070: 2014 Section 8.5
Peak tensile force of guidewire	ISO 11070: 2014 Section 8.6
Torque strength	FDA Guidance In-house Standard
Torqueability (Torque control)	FDA Guidance In-house Standard
Tip Flexibility (Tip impact)	FDA Guidance In-house Standard
Coating Adherence /Integrity	FDA Guidance In-house Standard
Particulate test	FDA Guidance In-house Standard
Ease of removing from the holder	In-house Standard
Sliding friction (hydrophilic coating portion)	In-house Standard
Sliding friction (PTFE coating portion)	In-house Standard
Proximal shaft stiffness	In-house Standard

The Radifocus Glidewire Advantage Track met the predetermined acceptance criteria. Based on the results of the performance testing, the proposed Radifocus Glidewire Advantage Track is substantially equivalent to the predicate.

Biocompatibility

In accordance with ISO 10993-1, the Radifocus Glidewire Advantage Track is classified as: Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours). This is the same classification as the predicate.

The finished device's patient contacting parts were tested in accordance with the tests recommended in the Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff issued on June 16, 2016. Screening tests were performed on accelerated aged devices to show that the biocompatibility is maintained throughout the shelf life of the product.

The **Table 5** below provides a list of biocompatibility tests conducted on the proposed Radifocus Glidewire Advantage Track.

Table 5: Summary of ISO 10993 Biocompatibility Testing

Non-aged, sterile, whole device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity
Pyrogenicity
Hemolysis
Thrombogenicity
Complement Activation (Immunology)
Physicochemical Profile (Physicochemical and FT-IR)
Accelerated-aged (2 years), sterile, whole device
Cytotoxicity
Hemolysis
Physicochemical Profile (Physicochemical and FT-IR)

Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

Sterilization

The sterility of the device is assured using a sterilization method validated in

accordance with ISO 11135:2014, *Sterilization of Health Care Products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices*, to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) will meet requirements for limited exposure devices (contact up to 24 hours) prior to use based on ISO 10993-7, *Biological Evaluation of medical devices- Part 7: Ethylene Oxide Sterilization residuals*.

Residual EO will not exceed 4 mg per device and residual ECH will not exceed 9 mg per device after 24 hours of aeration.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971: 2007, taking into account the modifications to the previous device, and it was determined that there were no new issues of safety or effectiveness.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) does not include data from clinical tests.

J. CONCLUSION (807.92(b)(3))

In summary, the Radifocus Glidewire Advantage Track, subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device:

- K122590 and K063372 – Radifocus Glidewire Advantage, manufactured by Ashitaka Factory of Terumo Corporation