



Food and Drug Administration
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November 16, 2015

Terumo Medical Corporation
% Phebe Varghese
Regulatory Affairs Specialist
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Re: K152740

Trade/Device Name: Radifocus Glidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 23, 2015
Received: September 23, 2015

Dear Ms. Varghese:

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 yours,

Kenneth J. Cavanaugh -S

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)

K152740

Device Name

Radifocus Glidewire®

Indications for Use (Describe)

The Glidewire 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

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

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Date prepared: November 10, 2015

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

Proprietary Name: Radifocus Glidewire®
Common Name: Guide wire
Classification Name: Wire, Guide, Catheter
Classification Panel: Cardiovascular
Regulation: 21 CFR 870.1330
Product Code: DQX
Classification: Class II

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

The legally marketed device to which substantial equivalence is claimed is:

- K863138 – Terumo Radifocus Guide Wire, manufactured by Ashitaka Factory of Terumo Corporation
- Additional reference device: K151471 – Terumo Radifocus Glidewire Endoscopic Wire

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the Radifocus Glidewire, manufactured by Ashitaka Factory of Terumo Corporation, is to extend the product size range to include 260, 300, 350, 400, and 450cm lengths.

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

Principle of Operation Technology

The Radifocus Glidewire is operated manually or by manual process.

Design/Construction

The Radifocus Glidewire is a guide wire which is designed to fit inside a percutaneous catheter for the purpose of directing a catheter through the blood vessel. It is provided sterile and is intended for single use only. It consists of a Nickel Titanium alloy core wire; a polyurethane coating (containing tungsten) and a hydrophilic polymer coating are applied to the entire wire. There are two shaft configurations: standard and stiff. There are two distal tip shapes: straight and angled, and two types of flexible part lengths of the tip: 3 and 5cm. The Radifocus Glidewire is packaged in a plastic holder that is contained within an individual package. A guide

wire inserter is included within the individual package to assist with the insertion of the guide wire into a catheter.

Materials

The materials for the Radifocus Glidewire are provided in the table below.

Table 5.1: Radifocus Glidewire Materials (All Wire Lengths)

Part		Raw Material	
Guide wire	Core wire		Nickel-Titanium alloy
	First coating*		Tungsten
			Polyurethane containing Tungsten
	Second coating*	Hydro gel	Hydrophilic polymer (Half-ester methyl vinyl ether-maleic anhydride copolymer)
Under coat		Polyvinyl chloride	
Guide wire inserter		Polyethylene	

* Blood contacting material

Specifications

The specifications for the Radifocus Glidewire are provided in the table below.

Table 5.2: Radifocus Glidewire Specifications

Part	Specification
Diameter of Wire	0.035"
Length of Wire	260, 300, 350, 400, and 450cm
Distal Tip Shape	Straight, Angled
Accessory Device	Guide wire inserter

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

The Glidewire 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 intended use is identical to the predicate device, Terumo Radifocus Guide

Wire (K863138).

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

The Radifocus Glidewire, subject of this 510(k), is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, and performance to the Terumo Radifocus Guide Wire, cleared under K863138, manufactured by Ashitaka Factory of Terumo Corporation.

This device is also identical to the Radifocus Glidewire Endoscopic Wire (K151471) device and differs only in indication for use.

A comparison of the technological characteristics is summarized on the table below.

Table 5.3: Summary of Comparative Information

Device Characteristic		New Device: Radifocus Glidewire	Predicate: Terumo Radifocus Guide Wire (K863138)
<i>Manufacturer</i>		Ashitaka Factory of Terumo Corporation	Same
<i>Indication for Use</i>		The Glidewire 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.	The Glidewire is designed to direct a catheter to the desired anatomical location during diagnostic or interventional procedures.
<i>Operation Principle</i>		Manual	Same
<i>Design/Construction</i>		Fully hydrophilic guide wire	Same
<i>Materials</i>	<i>Guide wire</i>	<ul style="list-style-type: none"> • Core wire: <ul style="list-style-type: none"> ○ Nickel-Titanium alloy • First Coating: <ul style="list-style-type: none"> ○ Polyurethane containing Tungsten <ul style="list-style-type: none"> ▪ Tungsten ▪ Polyurethane • Second Coating: <ul style="list-style-type: none"> ○ Hydro gel <ul style="list-style-type: none"> ▪ Hydrophilic polymer ○ Under coat <ul style="list-style-type: none"> ▪ Polyvinyl chloride 	Same

Device Characteristic		New Device: Radifocus Glidewire	Predicate: Terumo Radifocus Guide Wire (K863138)
	Guide wire inserter	Polyethylene	
Specifications		Diameter: 0.035"	Diameter: 0.018-0.052"
		Lengths: 260, 300, 350, 400, and 450cm	Lengths: 30-300cm
		Shaft configurations: standard and stiff	Same
		Distal tip shape: straight and angled	Same
		Flexible part lengths of the tip: 3 and 5cm	Flexible part lengths of the tip: 1, 3, 5 and 8 cm
Package	<ul style="list-style-type: none"> • Individual package • Unit box • Shipping carton 	Same	
Sterilization	Ethylene oxide	Same	
Shelf - life	24 months	Same	

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

Performance

Testing was conducted to ensure the performance of the Radifocus Glidewire throughout the labeled shelf life, verify conformity to the applicable parts of ISO standard and demonstrate substantial equivalence to the predicate device. With the exception of the Radiodetectability¹ test, the following performance tests were performed on non-aged and accelerated aged Radifocus Glidewire samples. All samples tested met the standard applicable to each test, and no new issues of safety and effectiveness were raised with the testing performed.

Table 5.4: Performance Testing per ISO Standard

Test	Standard
Surface	Section 4.3 of ISO 11070:2014
Radiodetectability	Section 4.5 of ISO 11070:2014
	ASTM F640-12
Fracture Test	Section 8.4 of ISO 11070:2014
Flexing Test	Section 8.5 of ISO 11070:2014
Peak Tensile Force of Guidewire	Section 8.6 of ISO 11070:2014

¹ Only non-aged sample was tested since there is no change over time on the radiopaque metal material.

Additionally, performance testing other than that recommended in the above ISO standard was performed on the device in accordance with FDA guidance documents and/or Terumo’s in-house standards. The subject device complies with the acceptance criteria established based on the predicate device and/or the FDA guidance documents, as shown in the table below.

Table 5.5: Performance Testing per FDA Guidance Documents and/or In-house Standards

Test	Standard
Peak Tensile Force of Guidewire	3.a of Coronary and Cerebrovascular Guidewire Guidance, January 1995
Torque Strength	3.b of Coronary and Cerebrovascular Guidewire Guidance, January 1995
	In-house Standard
Torqueability	3.c of Coronary and Cerebrovascular Guidewire Guidance, January 1995
	In-house Standard
Tip Flexibility	3.d of Coronary and Cerebrovascular Guidewire Guidance, January 1995
	In-house Standard
Sliding Resistance/Coating Integrity (Product Appearance)	3.e of Coronary and Cerebrovascular Guidewire Guidance, January 1995
	In-house Standard
Particulate Evaluation	VIII.A.13 of Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010
	USP<788>
	In-house Standard
Product Dimension	In-house Standard

Performance testing demonstrated that the Radifocus Glidewire conformed to the recognized consensus ISO standard and FDA guidance documents, is substantially equivalent to the predicate device, and is acceptable for clinical use throughout its shelf life.

Biocompatibility

In accordance with ISO 10993-1:2009, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*, the Radifocus Glidewire is classified as: Externally Communicating Devices, Circulating blood,

Limited Contact (<24 hrs). This is the same classification as the predicate Terumo Radifocus Guide Wire (K863138).

All the materials from the subject device are the same as the predicate device. The subject and predicate devices have the same intended use/indications for use, body contact, and contact duration classification, based on ISO 10993-1:2009. Additionally, the Terumo Radifocus Guide Wire product line has a demonstrated history of safe and effective use in the clinical setting. Therefore, Terumo concludes that the Radifocus Glidewire is biocompatible for its intended use.

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 development, validation and routine control of a sterilization process for medical devices*, to provide a Sterility Assurance Level (SAL) of 10^{-6} .

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971:2007, *Medical devices- Application of risk management to medical devices*, 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, subject of this 510(k), is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, and performance to the predicate device:

K863138 – Terumo Radifocus Guide Wire, manufactured by Ashitaka Factory of Terumo Corporation.

There are no significant differences that raise any new issues of safety and effectiveness.