



Food and Drug Administration
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September 17, 2015

Terumo Medical Corporation
Phebe Varghese
Regulatory Affairs Specialist
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Re: K151471
Trade/Device Name: Radifocus Glidewire Endoscopic Wire
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: August 11, 2015
Received: August 11, 2015

Dear Phebe 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,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151471

Device Name

Radifocus Glidewire Endoscopic Wire

Indications for Use (Describe)

The Radifocus Glidewire Endoscopic Wire is intended to be used for selective cannulation of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

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.

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510(k) SUMMARY

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

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Date prepared: May 29, 2015

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

Proprietary Name: Radifocus Glidewire® Endoscopic Wire
Common Name: Endoscopic Guidewire
Classification Name: Endoscopic Guidewire, Gastroenterology-Urology
Classification Panel: Gastroenterology/Urology
Regulation: 21 CFR 876.1500
Product Code: 78 OCY
Classification: Class II

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

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

K910722 – 450cm Guide Wire for G.I. Use, manufactured by Ashitaka Factory of Terumo Corporation.

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the Radifocus Glidewire Endoscopic wire, to include 2 smaller diameters and one length that were not included in the original 450cm Guide Wire for G.I. Use (K910722) submission. This submission also includes a clear indication for use statement.

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

Principle of Operation Technology

The Radifocus Glidewire Endoscopic Wire is operated manually or by manual process.

Design/Construction

The Radifocus Glidewire Endoscopic Wire is an endoscopic guide wire that is provided sterile and is intended for single use only. It consists of a Nickel Titanium alloy core wire, and a polyurethane containing tungsten and hydrophilic polymer that are applied to the entire wire. There are two shaft configurations: standard and stiff;

the stiff shaft has a slightly thicker core wire than that of the standard shaft. The wire distal segment comes in angled or straight configurations and is packaged in a plastic holder that is contained within an individual package. A guide wire inserter is contained within the individual package to assist with the insertion of the wire into an endoscope or catheter.

Materials

The materials for the Radifocus Glidewire Endoscopic Wire are provided in **Table 5.1** below.

Table 5.1: Radifocus Glidewire Endoscopic Wire Materials (All Wire Diameters)

Part		Raw Material	
Guide Wire	Core Wire	Nickel-Titanium Alloy	
	First Coating*	Polyurethane containing Tungsten	Tungsten
			Polyurethane
	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 Endoscopic Wire are provided in

Table 5.2 below.

Table 5.2: Radifocus Glidewire Endoscopic Wire Specifications

Part	Radifocus Glidewire Endoscopic Wire
Diameter of Wire	0.020”, 0.025”, 0.035”
Length of Wire	260 cm and 450 cm
Distal Tip Shape	Straight, Angled
Accessory Device	Guide wire inserter

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

The Radifocus Glidewire Endoscopic Wire is intended to be used for selective cannulation of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges.

Note: The indication for use statement was not included for the submission of 450cm Guide Wire for G.I. Use (K910722); however, the intended use of the subject device is identical to that of the predicate device.

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

The Radifocus Glidewire Endoscopic Wire, the subject device of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the 450cm Guide Wire for G.I. Use, cleared under K910722, manufactured by Ashitaka Factory of Terumo Corporation.

A comparison of the technological characteristics is summarized in **Table 5.3** below.

Table 5.3: Summary of Comparative Information between Radifocus Glidewire Endoscopic Wire and 450cm Guide Wire for G.I. Use (K910722)

Device Characteristic		New Device: Radifocus Glidewire Endoscopic Wire	Predicate: 450cm Guide Wire for G.I. Use (K910722)
Manufacturer		Ashitaka Factory of Terumo Corporation	same
Indication for Use		The Radifocus Glidewire Endoscopic Wire is intended to be used for selective cannulation of the biliary ducts, including but not limited to, the common bile, cystic, right and left hepatic ducts during endoscopic biliary procedures for catheter introduction and exchanges	Guide wire for gastrointestinal use Note: Indication for Use was not included at the time of 510(k) submission
Principle of Operation/Technology		Manual	same
Specifications		Diameter: 0.020”, 0.025”, 0.035”	Diameter: 0.032” and 0.035”
		Length: 260cm and 450cm	Length: 400cm and 450cm
Materials	Guide wire	<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 (Half-ester methyl vinyl ether-maleic anhydride copolymer) ○ Under coat <ul style="list-style-type: none"> ▪ Polyvinyl chloride 	same
	Guide wire inserter	Polyethylene	
Radiopacity		Radiopaque under fluoroscopy	same

Device Characteristic	New Device: Radifocus Glidewire Endoscopic Wire	Predicate: 450cm Guide Wire for G.I. Use (K910722)
<i>Packaging Material</i>	Polyester-polyethylene laminated film and paper	same
<i>Sterilization</i>	Ethylene Oxide	same
<i>Shelf - life</i>	24 months	same

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

Performance

Performance testing was conducted to ensure the safety and effectiveness of the Radifocus Glidewire Endoscopic Wire throughout the device’s shelf life, verify conformity to the applicable ISO standards, and demonstrate substantial equivalence to the predicate device.

No new issues of safety and effectiveness were raised with the testing performed.

The following tests were performed on non-aged and accelerated aged samples according to currently accepted ISO 11070: 2014 Sterile single-use intravascular introducers, dilators and guidewires.

Table 5.4: Performance Testing per ISO Standards

Test	Standard
Radiodetectability	ISO 11070, Section 4.5
Fracture Test	ISO 11070, Section 8.4
Flexing Test	ISO 11070, Section 8.5
Peak Tensile Force of Guidewire	ISO 11070, Section 8.6

All samples tested met the standard applicable to each test.

Additionally, performance testing other than to the above ISO Standard was performed on the device in accordance with Terumo’s internal standards. The device complies with the acceptance criteria established for each test based on the predicate.

Table 5.5: Performance Testing per Internal Standards

Performance Test	Results
Flexibility Test of Distal Tip	Meets acceptance criteria
Torque transmission	Meets acceptance criteria
Sliding Resistance/Coating Integrity (Product appearance)	Meets acceptance criteria
Bending Strength	Meets acceptance criteria

Performance testing demonstrates that the Radifocus Glidewire Endoscopic Wire conforms to the ISO standard and is substantially equivalent to that of the predicate device and is safe and effective for its intended use.

Biocompatibility

In accordance with ISO 10993-1, the Radifocus Glidewire Endoscopic Wire is classified as Externally Communicating Device, Tissue/bone/dentin communicating, Limited Contact (<24 hrs). This is the same classification as the predicate 450cm Guide Wire for G.I. Use (K910722).

All of the subject device’s materials are the same as the predicate device. These devices have the same intended use, body contact, and contact duration classification based on ISO 10993-1: 2009. Additionally the 450cm Guide Wire for G.I. Use product line have a demonstrated history of safe and effective use. We conclude, therefore, that the Radifocus Glidewire Endoscopic Wire is biocompatible for its intended use.

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135, *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} . 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.

Pyrogen Testing

The Radifocus Glidewire Endoscopic Wire is certified to be non-pyrogenic in the unopened and undamaged package. Limulus Amebocyte Lysate (LAL) (Photometric Quantitative Method) testing is performed on each lot of product in accordance to the United States Pharmacopoeia (USP) <85> Bacterial Endotoxins Test. Validation was performed in accordance with FDA published “Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers; June 2012”.

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 issues of safety and 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 Endoscopic Wire, subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device(s):

K910722 – 450cm Guide Wire for G.I. Use, manufactured by Ashitaka Factory of Terumo Corporation.

There is no significant difference that raises any new issues of safety and effectiveness.