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

September 15, 2017

Terumo Medical Corporation
Ms. Monika McDole-Russell, MSRA, RAC
Manager, Regulatory Affairs
265 Davidson Ave., Suite 320
Somerset, New Jersey 08873

Re: K170417
Trade/Device Name: Glidewire GT
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: September 1, 2017
Received: September 5, 2017

Dear Ms. McDole-Russell:

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 (DICE) 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 (DICE) 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,

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

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)*
K170417

Device Name
Glidewire GT

Indications for Use *(Describe)*
The Glidewire GT 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))

Prepared by/

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Registration No: 968 183 4

Date prepared: September 12, 2017

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

Proprietary Name:	Glidewire® GT
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

The reference predicate is:

K122590 – Radifocus Glidewire Advantage manufactured by Ashitaka Factory of Terumo Corporation.

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for a new guide wire for peripheral use for the purpose of establishing substantial equivalence to a legally marketed predicate device.

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

Principle of Operation Technology

The Glidewire® GT is operated by manual process.

Design/Construction

The Glidewire® GT is a guide wire which is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures. It is provided sterile and is intended for single use only. The Glidewire® GT consists of a core wire of a Nickel Titanium superelastic alloy and has a flexible radiopaque gold coil around the distal tip of the core wire. The Glidewire® GT is offered with two distal tip types: Shapeable and Preshaped.

The wire distal segment comes in angled or straight configurations. Physicians choose the guide wire types depending upon their personal preference and the type of interventional procedure being performed. Other considerations may include: anatomy, difficulty of access, and the interventional device used for procedure.
The device is packaged in a plastic holder that is contained within an individual package. A guide wire inserter, torque device and mandrel (Shapeable type only) are contained within the individual package to assist with the manipulation of the guide wire. Following the guide wire insertion, the guide wire inserter is removed from the proximal portion of guide wire.

Specifications

The specifications for the Glidewire® GT are provided in the table below.

Table 5.1: Glidewire® GT Specifications

Part	Specification
Diameter of Guide Wire	0.014”, 0.016”, 0.018”
Length of Guide Wire	180 cm, 200 cm
Distal Shape Processing Type	Preshaped, Shapeable
Tip configuration	Straight, Angled (Angled (45°, 90°), Double Angled, Large curve)
Accessory Device	Guide Wire Inserter, Torque Device, Mandrel* *: Mandrel is only included with the Shapeable type.

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

The Glidewire® GT 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.

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

The Glidewire® GT, 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.

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

Table 5.2: Summary of Comparative Information

Device Characteristic	**New Device:** Glidewire® GT	**Predicate:** Terumo Radifocus Guide Wire (K863138)	**Reference predicate:** Radifocus Glidewire Advantage (K122590)
Manufacturer	Ashitaka Factory of Terumo Corporation	Same	Same
Indication for Use	The Glidewire® GT 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 in the vasculature system during diagnostic or interventional procedures.	The Radifocus Glidewire Advantage is designed to direct a catheter to the desired anatomical location in the peripheral vasculature during diagnostic or interventional procedures.
Operation Principle	Manual	Same	Same
Design/Construction	Core wire is Nickel-Titanium alloy Fully hydrophilic coating 1) tungsten/polyurethane, 2) hydrophilic polymer Gold coil radiopaque maker	Same Same Not available	Same Hydrophilic coating, distal: tungsten/polyurethane; proximal: PTFE Same as the subject device

Device Characteristic	**New Device:** Glidewire® GT	**Predicate:** Terumo Radifocus Guide Wire (K863138)	**Reference predicate:** Radifocus Glidewire Advantage (K122590)
Specifications	• O.D.: 0.014", 0.016", 0.018" • Lengths: 180cm, 200cm • Tip configuration: Straight and Angled (Angled (45°, 90°), Double Angled, Large curve) • Distal shape processing type: Preshaped, Shapeable	• O.D.: 0.018"-0.052" • Lengths: 30-300cm • Tip configuration: Straight and Angled (including but not limited to 45°, 90°, Double Angled) • Distal shape processing type: Preshaped, Shapeable	• O.D.: 0.014" • Lengths: 180cm, 300cm • Tip configuration: Angled (Angled (45°)) • Distal shape processing type: Preshaped
Package Material	• Individual package Polyester-polyethylene laminated film and paper • Unit box • Shipping carton	Same Same Same	Similar Polyester-polyethylene laminated film and Tyvek Same Same
Sterilization	Ethylene oxide	Same	Same
Shelf-life	24 months	Same	Same

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

Performance

Performance testing was conducted to evaluate the performance of the Glidewire® GT throughout the labeled shelf life, verify conformity to applicable standards and demonstrate substantial equivalence to the predicate devices. With the exception of the Radiodetectability[1] test, the following performance tests were performed on non-aged and accelerated-aged Glidewire® GT samples. All samples tested met the applicable acceptance criteria, and no new issues of safety and effectiveness were raised by the testing performed.

[1] Only baseline testing was performed since no change in the radiopacity of the gold markers is anticipated with aging.

Table 5.3: Performance Testing per ISO Standard

Test Item	Reference
Surface	Sec. 4.3 of ISO 11070: 2014
Radiodetectability[2]	Sec. 4.5 of ISO 11070: 2014, ASTM F640-12
Fracture Test	Sec. 8.4 of ISO 11070: 2014
Flexing Test	Sec. 8.5 of ISO 11070: 2014
Peak Tensile Force of guidewire	Sec. 8.6 of ISO 11070: 2014

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

Test Item	Reference
Peak Tensile Force of guidewire	3.a of FDA Guidance[3], In-house Standard
Torque strength	3.b of FDA Guidance[3], In-house Standard
Torqueability	3.c of FDA Guidance[3], In-house Standard
Tip flexibility	3.d of FDA Guidance[3], In-house Standard
Sliding resistance/Coating integrity (Product appearance)	3.e of FDA Guidance[3], In-house Standard
Particulate evaluation	VIII.A.13 of FDA Guidance[4], USP <788>, In-house Standard
Product dimension	In-house Standard
Shaping test	In-house Standard

Performance testing demonstrated that the Glidewire® GT conformed to the

[2] Only baseline testing was performed since no change to the radiopacity of the gold markers is anticipated with aging.
[3] *Coronary and Cerebrovascular Guidewire Guidance, January 1995*
[4] *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010*

recognized consensus ISO standards, FDA guidance documents or in-house standards, is substantially equivalent to the predicate device for 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 Glidewire® GT is classified as an Externally Communicating Devices, Circulating blood, Limited Contact (<24 hrs). This is the same classification as the predicate Terumo Radifocus Guide Wire (K863138) which is intended for vascular use.

All the blood contacting materials from the subject device are the same as the predicate Terumo Radifocus Guide Wire (K863138) and the Radifocus Glidewire (K152740) which are intended for vascular use. The subject and predicate devices have the same intended use, body contact, and contact duration classification, based on ISO 10993-1: 2009. Additionally, the predicate product lines have a demonstrated histories of safe and effective use in the clinical setting. Therefore, Terumo concludes that the Glidewire® GT is biocompatible for its intended use based on biocompatibility testing leveraged from the predicate device.

Sterilization

The device was adopted into an existing sterilization cycle that was 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 no new risks were identified.

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 Glidewire® GT, 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:

1. Primary Predicate:
   K863138 – Terumo Radifocus Guide Wire, manufactured by Ashitaka Factory of Terumo Corporation

2. Reference Predicate:
   K122590 - Radifocus Glidewire Advantage manufactured by Ashitaka Factory of Terumo Corporation.

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