November 26, 2024

Terumo Medical Corporation
Qing Liu
Regulatory Affairs Specialist
265 Davidson Avenue, Suite 320
Somerset, New Jersey 08873

Re: K240818
Trade/Device Name: R2P Radifocus Glidewire Advantage
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 25, 2024
Received: November 1, 2024

Dear Qing Liu:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Samuel G. Raben -S

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240818

Device Name

R2P Radifocus Glidewire Advantage

Indications for Use *(Describe)*

The R2P Radifocus Glidewire Advantage 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.

510(K) SUMMARY

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

Prepared by: Qing Liu
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Prepared for: ***Owner/Operator***
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Date prepared: March 25, 2024

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

Proprietary Name:	R2P Radifocus Glidewire Advantage
Common Name:	Guide Wire
Classification Name:	Catheter Guide Wire
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:

Predicate Device: K152740 – Radifocus Glidewire, manufactured by Ashitaka Factory of Terumo Corporation.

Reference Devices:

- K063372 Radifocus Glidewire Advantage, Ashitaka Factory of Terumo Corporation
- K163004 Radifocus Glidewire Advantage Track, Ashitaka Factory of Terumo Corporation
- K033742 BOSTON SCIENTIFIC V-18 CONTROL WIRE, BOSTON SCIENTIFIC CORP
- K172073 Hi-Torque Command 18 Guide Wire, Abbott Vascular
- K150445 ASAHI Peripheral Guide Wires (ASAHI Gladius, ASAHI Halberd, and ASAHI Gaia PV), ASAHI Intecc Co., Ltd.

D. REASON FOR 510(k) SUBMISSION

This traditional 510(k) for R2P Radifocus Glidewire Advantage is being submitted for a new device for the purposes of establishing substantial equivalence to a legally marketed predicate device.

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

Principle of Operation Technology

The subject device, R2P Radifocus Glidewire Advantage, and the predicate device, Radifocus Glidewire (K152740), are both operated through a manual process.

Design/Construction

The subject device, R2P Radifocus Glidewire Advantage, and the predicate device, Radifocus Glidewire (K152740), exhibit some differences in design and construction.

Terumo has confirmed that these differences don't introduce any new concerns in safety and performance compared to the predicate device.

Table 1 provides details on the materials used in the construction and **Table 2** provides specifications of R2P Radifocus Glidewire Advantage.

Table 1: List of Materials

Raw material		**Patient contact**
0.018"	0.035"	Direct
Stainless steel	Nickel-Titanium alloy	
Nickel-Titanium alloy		Direct
Polyurethane containing tungsten		Direct
Hydrophilic polymer		Direct
Polytetrafluoroethylene (PTFE)		Non-contact
Polytetrafluoroethylene (PTFE)/ Colorant		Direct
Platinum/ Iridium (Pt/Ir)		Direct
Tin/Silver (Sn/Ag)		Direct
Gold (Au)	None	Non-contact
Modified acrylate	None	Non-contact
Silicone oil		Indirect
Polyethylene		Indirect
Polypropylene		Non-contact
Polypropylene/ Colorant		Indirect
Syrene-ethylenebutylene-styrene block copolymer		Indirect

Specifications

Table 2: Specifications

Part	Specification		
Diameter of Wire	0.018”	0.035”	
Length of Wire	400, 450 and 500cm	350, 400, and 450cm	
Distal Tip Shape	Angled	Angled	J Shaped (Available only in 400 and 450cm lengths)
Accessory Device	Guide wire inserter, Guide wire clip		

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

The R2P Radifocus Glidewire Advantage 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))

R2P Radifocus Glidewire Advantage, the subject device of this Traditional 510(k), is substantially equivalent in its Intended Use/Indication for Use and Technological Characteristics to the predicate device, **Radifocus Glidewire (K152740)**.

In addition to the above-listed primary predicate, Terumo has identified the following reference devices. These are market leading devices with the similar intended use and basic design as the subject device.

- K063372 Radifocus Glidewire Advantage, Ashitaka Factory of Terumo Corporation
- K163004 Radifocus Glidewire Advantage Track, Ashitaka Factory of Terumo Corporation

The comparison of the technological characteristics is summarized in **Table 3.A and 3.B**.

Table 3.A: 0.035" vs. Predicate Device and Reference Device 1

Comparison of Device Characteristics	**Subject device:** R2P Radifocus Glidewire Advantage	**Predicate Device:** Radifocus Glidewire(K152740)	**Reference Device 1:** Radifocus Glidewire Advantage (K063372)
Manufacturer	Ashitaka Factory of Terumo Corp.	Same	Same
Intended Use/Indication for Use	The R2P Radifocus Glidewire Advantage 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.	Same	The 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	The R2P Radifocus Glidewire Advantage (0.035") consists of a Nickel Titanium alloy core wire. A polyurethane and hydrophilic coating is applied to the distal portion of the wire.	Fully hydrophilic guide Wire	Same
	・Core wire (proximal portion) ・Core wire (intermediate portion) ・Core wire (distal portion) ・First coating (distal portion) ・Second coating (distal portion) Under coat ・PTFE spiral coating (intermediate portion) Under coating Top coating Spiral coating: ・Edge protection part Metal part Solder ・Silicone coating (proximal portion)	・Core wire ・First Coating ・Second Coating Under coat	・Core wire (proximal and distal portion) ・First coating (distal portion) ・Second coating (distal portion) Under coat ・PTFE spiral coating proximal portion) Under coating Top coating Spiral coating ・Edge protection part Metal part Solder Third coating on edge protection
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: 0.035" ・Length of Wire: 350,400,450 cm ・Shapes of Wire (distal tip) 350,400,450 cm: Angled 400,450 cm: J Shaped ・Accessory Devices: Guide wire inserter Guide wire clip	・Diameter of Wire: 0.035" ・Length of Wire: 260, 300, 350, 400, 450cm ・Shapes of Wire (distal tip) Angled, Straight ・Accessory Devices: Guide wire inserter	・Diameter of Wire: 0.018 - 0. 038" ・Length of Wire: 150 - 300 cm ・Shapes of Wire (distal tip): Angled, straight, J Shaped ・Accessory Devices: Guide wire inserter
Sterilization	Ethylene oxide	Same	Same
Shelf Life	24 months	Same	Same

Table 3.B: 0.018" vs. Predicate Device and Reference Device 2

Comparison of Device Characteristics	**Subject device:** R2P Radifocus Glidewire Advantage	**Predicate Device:** Radifocus Glidewire(K152740)	**Reference Device 2:** Radifocus Glidewire Advantage Track (K163004)
Manufacturer	Ashitaka Factory of Terumo Corp.	Same	Same
Intended Use/Indication for Use	The R2P Radifocus Glidewire Advantage 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.	Same	Same
Operation Principle	Manual	Same	Same
Design/ Construction	The R2P Radifocus Glidewire Advantage (0.018") consists of a Nickel Titanium alloy and stainless steel core wire. A polyurethane and hydrophilic coating is applied to the distal portion of the wire.	Fully hydrophilic guide Wire.	Same
	・Core wire (proximal portion) ・Core wire (intermediate portion) ・Core wire (distal portion) ・First coating (distal portion) ・Second coating (distal portion) Under coat ・PTFE spiral coating (intermediate portion) Under coating Spiral coating ・Edge protection part Metal part Solder ・Tip coil marker ・Tip coil marker adhesive ・Silicone coating (proximal portion)	・Core wire ・First Coating ・Second Coating Under coat	・Core wire (proximal portion) ・Core wire (distal portion) ・First coating (distal portion) ・Second coating (distal portion) Under coat ・PTFE spiral coating (proximal portion) Under coating Top coating Spiral coating ・Edge protection part Metal part Solder Third coating on edge protection ・Tip coil marker ・Tip coil marker adhesive
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: 0.018" ・Length of Wire: 400,450,500 cm ・Shapes of Wire (distal tip) Angled ・Accessory Devices: Guide wire inserter Guide wire clip	・Diameter of Wire: 0.035" ・Length of Wire: 260, 300, 350, 400, 450cm ・Shapes of Wire (distal tip) Angled, Straight ・Accessory Devices: Guide wire inserter	・Diameter of Wire: 0.014 and 0.018" ・Length of Wire: 180 and 300 cm ・Shapes of Wire (distal tip): Angled ・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 ensure the safety and effectiveness of R2P Radifocus Glidewire Advantage throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device.**Table 4** provides a list of performance tests that were performed on R2P Radifocus Glidewire Advantage.

Table 4: Summary of Performance Testing

Test Item
Dimensional Verification
Visual Inspection
Simulated Use
Tensile Strength and Tip Pull
Torque Strength
Torqueability
Coating integrity
Particulate evaluation
Lubricity
Corrosion resistance
Kink Resistance
Tip flexibility
Radiopacity

Performance testing met the predetermined acceptance criteria and is acceptable for clinical use throughout its shelf life.

Biocompatibility

In accordance with ISO 10993-1, R2P Radifocus Glidewire Advantage is classified as: Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours).

The finished device's patient contacting parts were tested in accordance with the tests recommended in the FDA *Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."*

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 R2P Radifocus Glidewire Advantage.

Table 5: Summary of ISO 10993 Biocompatibility Testing

Non-aged, sterile, whole device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Systemic Toxicity (Acute)
Pyrogenicity
Hemolysis (Direct and Indirect)
Complement Activation (SC5b-9)
In vivo Thrombogenicity
In vivo Thrombogenicity(HEPARINIZED)
Accelerated-aged (2 years), whole device
Cytotoxicity
Hemolysis (Direct and Indirect)
Physicochemical
FT-IR tests

Sterilization

The sterility of the device is assured using a sterilization method validated in accordance with ISO 11135:2014/Amd 1:2018, *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}.

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, **R2P Radifocus Glidewire Advantage**, subject of this 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate, **Radifocus Glidewire (K152740),** manufactured by Ashitaka Factory of Terumo Corporation.