August 21, 2024

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

Re: K240859
Trade/Device Name: Glidewire GT-R
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 28, 2024
Received: March 28, 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.

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.*

510(k) Number *(if known)*
K240859

Device Name
Glidewire GT-R

Indications for Use *(Describe)*
The Glidewire GT-R is intended 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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(K) SUMMARY

# Glidewire GT-R
# K240859

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

**Prepared by:** Qing Liu
Regulatory Affairs Specialist
Terumo Medical Corporation
Tel. (908) 842-9016
Fax (410) 398-6079

**Prepared for:** ***Owner/Operator***
Terumo Corporation
44-1, 2-Chome, Hatagaya
Shibuya-Ku, Tokyo
Japan 151-0072
Owner/Operator Number: 8010026

***Manufacturer and Sterilization Facility (Applicant)***
Ashitaka Factory of Terumo Corporation
150 Maimaigi-cho
Fujinomiya, Shizuoka 418-0015, Japan
Registration Number: 9681834

**Contact Person:** Qing Liu
Regulatory Affairs Specialist
Terumo Medical Corporation
265 Davidson Avenue, Suite 320
Somerset, NJ 08873
Tel. (908) 842-9016
Fax (410) 398-6079
E-mail: kyo.ryu@terumomedical.com

**Date prepared:** March 28, 2024

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

| | |
|---|---|
| *Proprietary Name:* | Glidewire GT-R |
| *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: K170417– Glidewire GT, manufactured by Ashitaka Factory of Terumo Corporation.

Reference Devices:

- K111498- Fathom 14 Steerable Guidewire manufactured by Boston Scientific Corporation
- K111485- Fathom 16 Steerable Guidewire manufactured by Boston Scientific Corporation
- K964611- Transend manufactured by Boston Scientific Corporation

## D. REASON FOR 510(k) SUBMISSION

This traditional 510(k) for Glidewire GT-R is being submitted for a new device for the purposes of establishing substantial equivalence to a legally marketed predicate device. The specification differences are the addition of a 220 cm Guide wire and a change in the individual packaging material.

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

***Principle of Operation Technology***

The subject device, Glidewire GT-R, and the predicate device, Glidewire GT (K170417), are both operated through a manual process.

***Design/Construction***

The subject device, Glidewire GT-R, and the predicate device, Glidewire GT (K170417), are the same design and construction except for Guide wire length.

***Materials***

The subject device, Glidewire GT-R, and the predicate device, Glidewire GT (K170417), are constructed from the same materials. The only material difference lies in the Individual Packaging.

**Table 1** provides details on the materials used in the construction of Glidewire GT-R.

**Table 1:** List of Materials

| No. | Raw Material | Patient Contact |
|---|---|---|
| 1 | Nickel-Titanium alloy | Non-contact |
| 2 | Gold | Non-contact |
| 3 | Polyurethane | Direct |
| 4 | Tungsten | |
| 5 | Hydrophilic polymer | Direct |
| 6 | Polyvinyl chloride | Direct |
| 7 | Acrylic resin | Non-contact |
| 8 | Polyvinyl chloride | Non-contact |
| 9 | Polyethylene | Indirect |
| | Colorant | |
| 10 | Polypropylene | Non-contact |
| 11 | Polypropylene | Indirect |
| | Colorant | |
| 12 | Polyethylene | Indirect |
| 13 | Styrene-ethylene-butylene-styrene block copolymer | Indirect |
| 14 | Polypropylene | Non-contact |
| 15 | Polyacetal | Non-contact |
| 16 | Stainless steel | Non-contact |
| 17 | Epoxy resin | Non-contact |
| 18 | Polypropylene | Non-contact |
| 19 | Polypropylene | Non-contact |
| 20 | Polyacetal | Non-contact |

***Specifications***

| | |
|---|---|
| Diameter of Wire: | 0.016", 0.018" |
| Length of Wire: | 180cm, 220cm |
| Distal Shape Processing Type | Preshaped, Shapeable |
| Tip Configuration: | Straight, Angled (45°, 90°), Double Angled |
| 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-R is intended 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))

**Glidewire GT-R**, the subject of this Traditional 510(k), is substantially equivalent in its Intended Use /Indications for Use , Technological Characteristics to the predicate, **Glidewire GT (K170417),** manufactured by Ashitaka Factory of Terumo Corporation.

In addition to the above-listed primary predicate, Terumo has identified the following reference devices. These are market leading devices with the same intended use and basic design as the subject device. Since these devices are frequently used in clinical practice, Terumo deemed it appropriate to use them as references when establishing the acceptance criteria for performance testing.

- K111498- Fathom 14 Steerable Guidewire manufactured by Boston Scientific Corporation
- K111485- Fathom 16 Steerable Guidewire manufactured by Boston Scientific Corporation
- K964611- Transend manufactured by Boston Scientific Corporation

The comparison of the technological characteristics is summarized in **Table 2**.

**Table 2:** Summary of Comparative Information

| Device Characteristics | Subject Device: Glidewire GT-R | Predicate Device: Glidewire GT (K170417) | Reference Device #1: Fathom"-14 Steerable Guidewire (K111498) | Reference Device #2: Fathom"-16 Steerable Guidewire (K111485) | Reference Device #3: Transend (K964611) |
|---|---|---|---|---|---|
| **Manufacturer** | Ashitaka Factory of Terumo Corporation | Same | Boston Scientific Corporation | Boston Scientific Corporation | Boston Scientific Corporation |
| **Intended Use /Indications for Use** | The Glidewire GT-R is intended 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® 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 FATHOM-14 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures. | The FATHOM-16 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures. | The Transend Guidewire is intended for general intravascular use, including the peripheral vasculature. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters. |
| **Operation Principle** | Manual | Same | Same | Same | Same |
| **Design/ Construction** | Fully hydrophilic Guide Wire | Same | Hydrophilic distal portion ; proximal portion is PTFE. | Hydrophilic distal portion ; proximal portion is PTFE. | Hydrophilic distal portion ; proximal portion is PTFE. |
| **Materials** | • Nickel-Titanium alloy<br>• Gold<br>• Tungsten<br>• Polyurethane<br>• Hydrophilic polymer<br>• Polyvinyl chloride<br>• Acrylic resin<br>• Polyvinyl chloride | Same | Information not publicly available. | Information not publicly available. | Information not publicly available. |
| **Specifications** | • O.D.: 0.016", 0.018" | • O.D.: 0.014", 0.016", 0.018" | • O.D.: 0.014" | • O.D.: 0.016" | • O.D.: 0.014", 0.018" |

| | | | | | |
|---|---|---|---|---|---|
| | • Lengths: 180cm, 220cm<br><br>• Tip configuration: Straight and Angled (Angled (45°, 90°), Double Angled)<br><br>• Distal shape processing type: Preshaped, Shapeable | • Lengths: 180cm, 200cm<br><br>• Tip configuration: Straight and Angled (Angled (45°, 90°), Double Angled, Large curve)<br><br>• Distal shape processing type: Same | • Lengths: 200cm, 300cm,<br><br>• Tip configuration: Straight and Angled<br><br>• Distal shape processing type: Shapeable | • Lengths: 140cm, 180cm, 200cm, 215cm,<br><br>• Tip configuration: Straight and Angled<br><br>• Distal shape processing type: Shapeable | • Lengths: 135cm, 165cm, 190cm<br><br>• Tip configuration: Straight<br><br>• Distal shape processing type: Shapeable |
| **Package Material** | • Individual package: Polyester-polyethylene lamination film and Polyethylene<br><br>• Unit box: Coated cardboard<br><br>• Shipping carton: Corrugated cardboard | • Individual package: Polyester-polyethylene lamination film and Paper<br><br>• Unit box: Same<br><br>• Shipping carton: Same | unknown | unknown | unknown |
| **Sterilization** | Ethylene oxide | Same | Same | Same | Same |
| **Shelf life** | 24 months | Same | unknown | unknown | unknown |

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

### *Performance Testing*

Performance testing was conducted to ensure the safety and effectiveness of Glidewire GT-R throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. Except for the Radio-detectability and Simulated Use tests, which were only performed on non-aged samples, the following performance tests were conducted on both non-aged and accelerated aged samples. **Table 3** provides a list of performance tests that were performed on Glidewire GT-R.

**Table 3:** Summary of Performance Testing

| Test Item |
|---|
| Dimensional Verification |
| Visual Inspection |
| Simulated Use |
| Tensile Strength |
| Tip Pull |
| Torque Strength |
| Torqueability |
| Lubricity and Coating Integrity |
| Particulate Evaluation |
| Kink Resistance |
| Tip Flexibility |
| Radiopacity |
| Shaping Test |
| Shape Retention |
| Corrosion resistance |

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

### *Biocompatibility*

In accordance with ISO 10993-1, Glidewire GT-R 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 4** below provides a list of biocompatibility tests conducted on Glidewire GT-R.

**Table 4:** 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 |
| Genotoxicity (Mouse Lymphoma Mutagenesis) |
| Genotoxicity (Bacterial Reverse Mutation) |
| Physicochemical |
| FT-IR |
| **Accelerated-aged (2 years), sterile, whole device** |
| Cytotoxicity |
| Hemolysis (Direct and Indirect) |
| Physicochemical |
| 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/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, **Glidewire GT-R**, subject of this 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate, **K170417** – **Glidewire GT**, manufactured by Ashitaka Factory of Terumo Corporation.