December 3, 2019

Terumo Medical Corporation
Liang Lu
Senior Regulatory Affairs Specialist
950 Elkton Blvd.
Elkton, Maryland 21921

Re: K193160
Trade/Device Name: Glidesheath Slender Tibial Pedal Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 14, 2019
Received: November 15, 2019

Dear Liang Lu:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Misti Malone
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193160

Device Name
Glidesheath Slender Tibial Pedal Kit

Indications for Use *(Describe)*
The Glidesheath Slender Tibial Pedal Kit is indicated to facilitate placing a catheter through the skin into the lower extremity peripheral vasculature below the knee.

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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"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

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

Prepared by:

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Date prepared: December 3, 2019

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

Proprietary Name:	Glidesheath Slender Tibial Pedal Kit
Common Name:	Introducer Sheath
Classification Name:	Catheter Introducer
Classification Panel:	Cardiovascular
Regulation:	21 CFR 870.1340
Product Code:	DYB
Classification:	Class II

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

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

- Predicate Device: K181237 – Glidesheath Slender Tibial Pedal Kit, manufactured by Terumo Medical Corporation

D. REASON FOR 510(k) SUBMISSION

This premarket notification (Special 510(k)) is being submitted to extend the current Glidesheath Slender Tibial Pedal Kit (7cm entry needle) product line to include a 4cm entry needle.

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

Both the predicate Glidesheath Slender Tibial Pedal Kit (7cm needle) and the modified Glidesheath Slender Tibial Pedal Kit (4cm needle) are used to facilitate placing a catheter through the skin into the lower extremity peripheral vasculature below the knee. It consists of an introducer (sheath and dilator), which are packaged together with a mini guide wire, an entry needle and a guide inserter.

During a diagnostic or interventional procedure in a cath lab, the stainless steel entry needle (cannula) is used to gain access to the vein or artery for placement of the mini guide wire. The nitinol mini guide wire is inserted through the cannula into the patient's blood vessel. The wire is used for placement of the sheath and dilator into the vein or artery. The Guide Inserter which is attached to the Mini Guide Wire holder is used to assist the placement of the wire into the needle.

Following guide wire insertion, the cannula is removed and the sheath and dilator are then inserted over the mini guide wire and into the blood vessel. The mini guide wire is then withdrawn from the vessel. The dilator maintains the integrity of the sheath and dilates the blood vessel during insertion. Once the sheath is situated in the vessel, the dilator is removed and an appropriate catheter can then be inserted through the sheath.

The sheath incorporates a 1-way valve and a 3-way stopcock connected by a side tube. The sheath is coated with hydrophilic coating to minimize frictional resistance when inserting or removing the sheath from the patient's blood vessel. In addition, the sheath and dilator contain bismuth, making these devices visible under fluoroscopy. The sheath, dilator, entry needle, mini guide wire and guide inserter are provided in a single package and sterilized together.

The Glidesheath Slender Tibial Pedal Kit is a disposable, ethylene oxide gas sterilized device intended for single use only.

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

The Glidesheath Slender Tibial Pedal Kit is indicated to facilitate placing a catheter through the skin into the lower extremity peripheral vasculature below the knee.

Note: The indications for use are identical to the predicate device, Glidesheath Slender Tibial Pedal Kit (K181237).

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

The Glidesheath Slender Tibial Pedal Kit, 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, manufactured by Terumo Medical Corporation.

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

Device Characteristic	**Predicate Device:** Glidesheath Slender Tibial Pedal Kit (K181237)	**Modified Device:** Glidesheath Slender Tibial Pedal Kit
Manufacturer	Terumo Medical Corporation	Same
Intended Use / Indications for Use	The Glidesheath Slender Tibial Pedal Kit is indicated to facilitate placing a catheter through the skin into the lower extremity peripheral vasculature below the knee.	Same
Operation Principle	Operated manually or by a manual process	Same
Design / Construction	Sheath, Dilator, Guide Wire, Guide Inserter, Entry Needle	Same
Materials	**Sheath assembly** Tube: Ethylene-Tetrafluoroethylene (ETFE) copolymer, Bismuth trioxide, Colorant, Silicone oil Hydrophilic Coating: Dimethyl acrylamide-glycidyl methacrylate copolymer Housing: Polypropylene Cap: Polypropylene Valve: Silicone Rubber Caulking Pin: Stainless Steel Sheath support: Styrene-ethylene-butylene-styrene block copolymer, Colorant Side tube: Polybutadiene <u>Three-way stopcock</u>: Holder: Polycarbonate; Cock: Polyethylene; Fastener pin: Polyethylene	**Sheath Assembly** Tube: Same Hydrophilic Coating: Same Housing: Same Cap: Same Valve: Same Caulking Pin: Same Sheath support: Same Side tube: Same <u>Three-way stopcock</u>: Holder: Same Cock: Same Fastener pin: Same

	Dilator assembly Tube: Polypropylene, Bismuth subcarbonate, Colorant, Silicone oil Hub: Polypropylene, Colorant Caulking Pin: Stainless steel	**Dilator Assembly** Tube: Same Hub: Same Caulking Pin: Same
	Mini guide wire Core: Nitinol (Nickel Titanium Alloy) Coil: Palladium Adhesive: Epoxy Adhesive	**Mini Guide Wire** Core: Same Coil: Same Adhesive: Same
	Guide inserter High-density polyethylene (HDPE), Colorant	**Guide inserter** Same
	Stainless steel entry needle Cannula: Stainless Steel, Silicone oil Hub: Styrene-Butadiene copolymer Protective Sleeve: Polypropylene	**Stainless steel entry needle** Cannula: Same Hub: Same Protective Sleeve: Same
Package	Unit Pouch Shelf Box Shipping Carton	Unit Pouch: Same Shelf Box: Same Shipping Carton: Same
Specifications	Sheath Size: 5 Fr. Sheath Length: 10 cm Hydrophilic Coating: full effective length (10 cm) Dilator applicable to Guide Wire OD: 0.021” Dilator Length: 15.7 cm Guide Wire OD: 0.021” Guide Wire Length: 43 cm Entry Needle Type: 21/19 (G) Entry Needle Length: 70 mm	Sheath Size: Same Sheath Length: Same Hydrophilic Coating: Same Dilator applicable to Guide Wire OD: Same Dilator Length: Same Guide Wire OD: Same Guide Wire Length: Same Entry Needle Type: Same Entry Needle Length: 70 mm, **40 mm**
Sterilization	Ethylene Oxide (validated in accordance with ANSI / AAMI / ISO 11135-1 to achieve SAL 10^{-6})	Same
Shelf life	30 months	Same
Disposable Single Use	Yes	Same

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

Performance

The design verification was performed via a Verification by Analysis. The Verification by Analysis demonstrates that the new 4cm needle in the Glidesheath Slender Tibial Pedal Kit meets the predetermined criteria (Product Specifications).

The differences between the predicate and proposed devices do not raise any new issues regarding safety and effectiveness. Therefore, no additional physical testing is required to ensure the safety and effectiveness of the proposed Glidesheath Slender Tibial Pedal kit throughout the shelf life.

Standards referenced in this Submission are provided in the **Table** below:

Standards Referenced in this Submission

Standard Designation	Standard Name	FDA Recognition # (if applicable)
ISO 10993-1: 2009 Cor. 1:2010	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process	2-220
ISO 10993-1: 2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2-258
ISO 10993-7: 2008 Cor.1:2009	Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals	14-408
USP 38 <85>	Bacterial Endotoxins Test (Sterility)	NA
ISO 11135: 2014	Sterilization of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices (Sterility)	14-452

Biocompatibility

There are no changes to materials or components for the Glidesheath Slender Tibial Pedal Kit, other than the transitory/transient patient contacting shorter needle length. Therefore, no additional biocompatibility testing was completed for the modified Glidesheath Slender Tibial Pedal Kit (4cm needle).

Sterilization

No changes have been made to the sterilization processes, packaging or shelf-life of the device relative to predicate. Sterilization information was leveraged from the predicate device.

Risk Analysis

A Product Risk Analysis was conducted in accordance with ISO 14971: 2012, taking into account the modifications to the previous device, and it was determined that there were no new or increased risks associated with the change.

I. CONCLUSION (807.92(b)(3))

In summary, the Glidesheath Slender Tibial Pedal kit, subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device:

- Predicate Device: K181237 – Glidesheath Slender Tibial Pedal Kit, manufactured by Terumo Medical Corporation