August 3, 2018

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

Re: K181237
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: April 24, 2018
Received: May 10, 2018

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. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Finn E. Donaldson -S

Digitally signed by Finn E. Donaldson -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000979673, cn=Finn E. Donaldson -S
Date: 2018.08.03 15:29:23 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181237

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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510(K) SUMMARY

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

Prepared by:

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Prepared for: ***Owner/Operator***

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Manufacturer (510(k) Applicant)

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Registration Number: 1118880

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Date prepared: August 3, 2018

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 are:

- Predicate Device: K142183 – Glidesheath Slender, manufactured by Terumo Corporation
- Reference Device 1: K152173 – Glidesheath, manufactured by Terumo Medical Corporation
- Reference Device 2: K111606 – Pinnacle Precision Access System, manufactured by Terumo Medical Corporation

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the Glidesheath Slender Tibial Pedal Kit, manufactured by Terumo Medical Corporation, for the purposes of establishing substantial equivalence to a legally marketed predicate device.

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

The Glidesheath Slender Tibial Pedal Kit is 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.

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 on the table below.

Table 1: Summary of Substantial Equivalence

Device Characteristic	**New Device:** Glidesheath Slender Tibial Pedal Kit	**Predicate:** Glidesheath Slender (K142183)
Manufacturer	Terumo Medical Corporation	Terumo Corporation
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.	The Glidesheath Slender is used to facilitate placing a catheter through the skin into the radial artery.
Operation Principle	Operated manually or by a manual process	Same
Design / Construction	Sheath, Dilator, Guide Wire, Guide Inserter, Entry Needle	Sheath, Dilator, Guide Wire, Guide Inserter, Entry Needle, Surflo IV catheter Note: Sheath and Dilator are Identical to the subject device
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** Identical Identical Identical Identical Identical Identical Identical Identical
	Dilator assembly Tube: Polypropylene, Bismuth subcarbonate, Colorant, Silicone oil Hub: Polypropylene, Colorant Caulking Pin: Stainless steel	**Dilator Assembly** Identical Identical Identical

	Mini guide wire Core: Nitinol (Nickel Titanium Alloy) Coil: Palladium Adhesive: Epoxy Adhesive	**Mini Guide Wire** Nitinol (Nickel Titanium Alloy), Tungsten, Polyurethane
	Guide inserter High-density polyethylene (HDPE), Colorant	**Guide inserter** Polyethylene
	Stainless steel entry needle Cannula: Stainless Steel, Silicone oil Hub: Styrene-Butadiene copolymer Protective Sleeve: Polypropylene	**Stainless steel entry needle** Cannula: Stainless Steel Hub: Polycarbonate Surflo IV Catheter: Ethylene-Tetrafluoroethylene (ETFE) copolymer, Barium sulfate; Polypropylene; Stainless Steel; Polystyrene, Polyester-Chlorinated polyvinyl chloride; Polycarbonate
Package	Unit Pouch Shelf Box Shipping Carton	Unit Pouch Shelf Box Shipping Carton
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: 15.5 cm Guide Wire OD: 0.021” Guide Wire Length: 43 cm Entry Needle Type: 21/19 (G) Entry Needle Length: 70 mm	Sheath Size: 5,6,7 Fr.; Sheath Length: 10,16 cm Hydrophilic Coating: full effective length (10, 16 cm) Dilator applicable to Guide Wire OD: 0.018,0.021,0.025,0.035” Dilator Length: 15.5 and 21.5 cm Guide Wire OD: 0.018,0.021,0.025,0.035” Guide Wire Length: 43,80 cm Entry Needle Type: 21/20 (G) Entry Needle Length: 35 mm Surflo IV Catheter Type: 18,20,22(G); Length: 25,32,51,64(mm)
Sterilization	Ethylene Oxide (validated in accordance with ISO 11135 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

All components of the Glidesheath Slender Tibial Pedal Kit come from the predicate device and reference devices. They are identical in materials, formulation, geometry, source (manufacturer), processing, chemicals, and intended patient exposure and utilize the same sterilization method (Ethylene Oxide) as those in the predicate devices and reference devices. All components are packaged together in a pouch, labeled, and sterilized as a finished good for the Glidesheath Slender Tibial Pedal kit. Therefore, no design verification testing was performed on the individual components to demonstrate the substantial equivalence of the proposed Glidesheath Slender Tibial Pedal kit.

Since the packaging configurations of the needle in the Glidesheath Slender Tibial Pedal Kit were different from the reference device (K152173), packaging testing was re-evaluated. The following packaging verification testing was performed to ensure the durability of the proposed Glidesheath Slender Tibial Pedal kit packaging throughout distribution:

- Visual Inspection (Post Environmental Conditioning and Distribution Simulation)

Cadaver Testing

To evaluate the clinical feasibility of the Glidesheath Slender Tibial Pedal kit, devices were tested in a simulated use situation using cadaver lower leg models to test arterial access at specific BTK (below-the-knee) arterial access sites. It was demonstrated that the Glidesheath Slender sheath is compatible with the insertion angles used in ultrasound guided BTK access protocols in the four BTK vessels tested. The study also demonstrated that the kit and its components are acceptable for use in BTK access. The study along with a follow-up survey confirmed that the protocols used by physicians in standard practice are equivalent to the access protocol used in the simulated use study. This provides confidence that the results from the testing are applicable to the broader BTK operator community. Therefore, the results of the feasibility study ensure the substantial equivalence of the proposed Glidesheath Slender Tibial Pedal kit.

Standards referenced in the testing of the proposed Glidesheath Slender Tibial Pedal kit by Terumo Medical Corporation are provided in Table 2 below.

Table 2: Standards Referenced in Testing of the Glidesheath Slender Tibial Pedal Kit

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 10993-7: 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
ASTM D4169-14	Standard Practice for Performance Testing of Shipping Containers and Systems	NA
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	14-484
ASTM F88/F88M-15	Standard Test Method for Seal Strength of Flexible Barrier Materials	14-482
ASTM F2825-10 (Reapproved 2015)	Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery	14-344

Biocompatibility

Biocompatibility classification is based on the FDA Guidance Use of International Standard ISO 10993-1, *"Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process."*

Glidesheath Slender Tibial Pedal kit is categorized as an external communicating device, circulating blood with limited contact duration (up to 24 hours). The biological evaluation of Glidesheath Slender Tibial Pedal kit was performed per EN ISO 10993-1 and FDA Guidance on Use of International Standard ISO 10993-1.

All components of the Glidesheath Slender Tibial Pedal kit are identical in materials, formulation, geometry, source (manufacturer), processing, chemicals, and intended patient exposure and utilize the same sterilization method (Ethylene Oxide) as those in the predicate device and reference devices. Therefore, no additional biocompatibility testing was performed, and the Glidesheath Slender Tibial Pedal kit is considered to have substantially equivalent biocompatibility for the indicated use.

Sterilization

Glidesheath Slender Tibial Pedal kit was adopted into an existing ethylene oxide sterilization process validated via the overkill half cycle approach in accordance with 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. The microbiological and performance qualifications for the existing sterilization process used for the reference devices were leveraged to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Glidesheath Slender Tibial Pedal kit is a limited exposure device. Sterilant residual testing was performed to demonstrate that after 24 hours of heated aeration, the level of residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) do not exceed an average daily dose of 4 mg and 9 mg respectively per EN ISO 10993-7:2008.

I. CLINICAL TESTS (807.92(b)(2))

This 510(k) included a summary of the PRIME Registry data. The first 71 patients treated with the Terumo Glidesheath Slender when undergoing an index endovascular procedure using a tibial access point was compared to a literature based dataset of procedures using radial and femoral access. No issues that may affect the determination of substantial equivalence were noted in the comparison.

J. 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.