May 8, 2018

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

Re: K173831
Trade/Device Name: Glidesheath Slender
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 13, 2018
Received: April 16, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 Kenneth J. Cavanaugh -S

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)*

K173831

Device Name
Glidesheath Slender

Indications for Use *(Describe)*
The Glidesheath Slender is indicated to facilitate placing a catheter through the skin into the radial artery.

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.

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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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Date prepared: April 27, 2018

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

Proprietary Name:	Glidesheath Slender
Common Name:	Introducer Sheath
Classification Name:	Introducer, Catheter
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, Japan
- Reference Device: K152173 – Glidesheath, manufactured by Terumo Medical Corporation, USA

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the Glidesheath Slender, 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 consists of an introducer (sheath and a dilator), which are packaged together with an entry needle, mini guide wire and guide wire inserter. The Glidesheath Slender devices (all sheath sizes) are used to facilitate placing a catheter through the skin into the radial artery. The sheath and dilator contain bismuth, making these devices visible under fluoroscopy. The sheath is coated with hydrophilic coating to minimize frictional resistance when inserting or removing the sheath from the patient's blood vessel.

The entry needle (cannula) is used to gain access to the radial artery for placement of the mini guide wire. The entry needle is offered in either the stainless steel (SS) entry needle version or the Surflo (SR) IV catheter (which includes a needle). There are two different types of stainless-steel entry needles that are available in various gauges and lengths. The two needle types are referenced in the documentation as TPC and TRI. These initials are only used in internal Terumo documents.

The mini guide wire is used for placement of the sheath and dilator into the radial artery. The mini guide wire is offered in three versions made out of three materials, either a stainless-steel spring coil model (stainless steel), a nitinol model with palladium tip (nitinol) or a polyurethane plastic model with a nitinol core (plastic).

During either a diagnostic or interventional catheterization procedure, a physician will perform the following procedure. The mini guide wire is inserted through a cannula placed in the patient's blood vessel. A guide wire inserter is provided to assist

in insertion of the mini guide wire into the cannula. 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 entry needle, the mini guide wire and the guide wire inserter are all accessories to the Glidesheath Slender sheath/dilator. The accessories for a given product code are provided with the Glidesheat Slender sheath/dilator in an individual package and sterilized together.

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

The Glidesheath Slender is indicated to facilitate placing a catheter through the skin into the radial artery.

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

The Glidesheath Slender, 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 Corporation.

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

Table 5.1: Summary of Substantial Equivalence

Device Characteristic	Subject Device: Glidesheath Slender	Predicate Device: Glidesheath Slender (K142183)
Manufacturer	Terumo Medical Corporation (Elkton, MD)	Terumo Corporation, (Ashitaka, Japan)
Intended Use / Indications for Use	The Glidesheath Slender is indicated to facilitate placing a catheter through the skin into the radial artery	Same
Operation Principle	Operated manually or by a manual process;	Same
Design / Construction	Sheath, Dilator, Guide Wires (Plastic, Stainless Steel, Nitinol), Surflo IV Catheter, Stainless Steel Entry Needle	Same, except for: Guide Wire (Nitinol) and TRI Stainless Steel Entry Needle of the proposed device are not available in kits for the predicate TC Glidesheath Slender (K142183), they are identical to the Guide Wire (Nitinol) and TRI Stainless Steel Entry Needle used in the reference Glidesheath (K152173).
Materials	**Sheath Assembly:** Ethylene-Tetrafluoroethylene(ETFE) copolymer Bismuth trioxide Colorant Dimethylacrylamide-glycidyl methacrylate copolymer Silicone oil Polypropylene Silicone Rubber Stainless Steel Styrene-ethylene-butylene-styrene block copolymer Polybutadiene Polycarbonate Polyethylene Colorant	Same, except for: 3WSC and Silicone Lubricant of the proposed device have same material types with minor differences, but they are identical to the 3WSC and Silicone Lubricant used in the reference Glidesheath (K152173).
	Dilator Assembly: Polypropylene Bismuth subcarbonate Colorant Silicone oil Stainless Steel	Same, except for: Silicone Lubricant of the proposed device has same material types with minor differences, but it is identical to the Silicone Lubricant used in the reference Glidesheath (K152173).

Device Characteristic	Subject Device: Glidesheath Slender	Predicate Device: Glidesheath Slender (K142183)
	Guide Wire (Plastic Jacket**):** Nickel-Titanium alloy Polyurethane Tungsten Silicone oil	Same
	Guide Wire (Stainless Steel**):** Stainless Steel	Same
	Guide Wire (Nitinol**):** Nickel-Titanium alloy Palladium Epoxy adhesive	Guide Wire (Nitinol) of the proposed device is not available in kits for the predicate TC Glidesheath Slender (K142183), but it is identical to the Guide Wire (Nitinol) used in the reference Glidesheath (K152173).
	Guide Wire Inserter: Polyethylene Colorant	Same
	Surflo IV Catheter: Ethylene-Tetrafluoroethylene (ETFE) copolymer Colorant Barium sulfate Dispersant Silicone oil Polypropylene Stainless Steel Sorbitan fatty acid ester Polycarbonate Polystyrene Polyester-Chlorinated polyvinyl chloride	Same
	Entry Needle (TPC): Stainless Steel Silicone oil Polycarbonate Acrylic resin containing colorant	Same

Device Characteristic	**Subject Device:** Glidesheath Slender	**Predicate Device:** Glidesheath Slender (K142183)
	Entry Needle (TRI): Stainless Steel Silicone oil Styrene-buadiene Acrylic resin heat transcription foil	Same, except for: TRI Stainless Steel Entry Needle (21G x 38mm) of the proposed device is not available in kits for the predicate TC Glidesheath Slender (K142183), but it is identical to the entry needle used in the reference Glidesheath (K152173).
Package	Tyvek, Polyester-polyethylene laminated film, High Impact Polystyrene	Same
Specifications	Sheath Size: 5, 6, 7 Fr. Length: 10, 16 cm Dilator Size (Applicable to GW Outer Diameter): 0.021, 0.025 inch Length: 15.7, 21.7 cm Guide Wire (Plastic) OD: 0.021, 0.025 inch Guide Wires Length: 45, 80 cm Guide Wire (Stainless Steel) OD: 0.021, 0.025 inch Guide Wires Length: 45, 80 cm Guide Wire (Nitinol) OD: 0.021 inch Guide Wires Length: 43 cm Surflo IV Catheter Type: 20, 22 G Length: 25, 32 mm (1”, 1 1/4”)	Sheath Same Dilator Size (Applicable to GW Outer Diameter): 0.018, 0.021, 0.025, 0.035 inch Length: 15.5, 21.5 cm Guide Wire (Plastic) OD: 0.018, 0.021, 0.025, 0.035 inch Guide Wires Length: Same Guide Wire (Stainless Steel) OD: 0.018, 0.021, 0.025, 0.035 inch Guide Wires Length: Same Guide Wire (Nitinol) None Surflo IV Catheter Type: 18, 20, 22 G Length: 25, 32, 51, 64 mm (1”, 1 1/4”, 2”, 2 1/2”)

Device Characteristic	**Subject Device:** Glidesheath Slender	**Predicate Device:** Glidesheath Slender (K142183)
	Entry Needle (TPC) Type: 20, 21 G Length: 35 mm Entry Needle (TRI) Type: 21 G Length: 38 mm	Entry Needle (TPC) Same Entry Needle (TRI) None TRI Stainless Steel Entry Needle (21G x 38mm) of the proposed device is not available in kits for the predicate TC Glidesheath Slender (K142183), but it is identical to the entry needle used in the reference Glidesheath (K152173).
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

Performance testing was conducted to ensure that the Glidesheath Slender met the applicable design and performance requirements throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device.

The following **Table 5.2** provides a list of the performance tests that were performed on the proposed Glidesheath Slender.

Table 5.2: Summary of Performance Testing

Component	Test Item	Reference
Sheath	Fluoroscopy	ISO 11070:2014, Section 4.5 ASTM F640-12
	Sheath visual inspection	In-house standard
	Sheath Effective Length	In-house standard
	Side Tube Length	In-house standard
	Sheath Tip ID	In-house standard
	Sheath, Hemostatic Valve Leak	ISO 11070:2014, Annex E
	Sheath Pressure Test	ISO 11070:2014, Annex D ISO 11070:2013, Annex C
	Sheath Penetration	In-house standard
	Visual inspection after penetration testing	ISO 11070:2014 - Annex A section A3
	Sheath Tip Rollback Test	ISO 11070:2014 - Annex A section A3
	Dilator Hub to Sheath Hub Snap Fit Strength	In-house standard
	Valve Mobility Resistance	In-house standard
	Sheath Kink resistance	ISO 11070:2014 Annex A section A.1
	Sheath Tubing/Housing Joint Strength	ISO 11070:2014, Section 7.6
	Cap to Housing Joint Strength	In-house standard
	Sheath Support to Housing Strength	In-house standard
	Sheath Tubing Tensile Strength	ISO 11070:2014, Section 7.6
	Sheath Lubricity and Durability	In-house standard
	Particle capture during simulated use	FDA PTCA Guidance
	Coating integrity after simulated use	In-house standard
Dilator	Fluoroscopy	ISO 11070:2014, Section 4.5 ASTM F640-12
	Dilator visual inspection	In-house standard
	Dilator Useable Length	In-house standard
	Dilator Tip ID	In-house standard
	Dilator OD at Sheath Tip	In-house standard
	Dilator Penetration	In-house standard
	Visual inspection after penetration testing	ISO 11070:2014 - Annex A section A3
	Dilator Tip Rollback Test	ISO 11070:2014 - Annex A section A3
	Dilator to Hub Tensile	ISO 11070:2014, Annex C ISO 11070:2013, Annex B
	Dilator Hub to Sheath Hub Snap Fit Strength	In-house standard
	Particle capture during simulated use	FDA PTCA Guidance

The Glidesheath Slender tested met the predetermined acceptance criteria and results support a determination of substantial equivalence. There are no new issues of safety and effectiveness in the performance of the device.

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

The proposed Glidesheath Slender product will have the same materials, processing, and sterilization as the existing Glidesheath (non-slender) product manufactured at TMC with the exception of the carrier solvent (manufacturing material) used for the hydrophilic coating of the sheath.

Due to the change in the carrier solvent used for the hydrophilic coating of the sheath, biocompatibility testing was performed on the Glidesheath Slender Introducer (sheath and dilator) to cover biological endpoints for the device categorization:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Pyrogenicity
- Hemocompatibility

Results of the testing demonstrate biocompatibility of the finished Glidesheath Slender. The Glidesheath Slender is considered to be biocompatible for the indicated use.

Sterilization
The sterility of the device is assured using a sterilization method validated 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 sterilization process was validated utilizing the overkill half cycle approach to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Glidesheath Slender is a limited exposure device. After 24 hours of heated aeration, the level of residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) shall 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) does not include data from clinical tests.

J. CONCLUSION (807.92(b)(3))

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

- Predicate Device: K142183 – Glidesheath Slender, manufactured by Terumo Corporation, Japan
- Reference Device: K152173 – Glidesheath, manufactured by Terumo Medical Corporation, USA