January 6, 2020

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

Re: K193125
Trade/Device Name: R2P Destination Slender Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: November 11, 2019
Received: November 12, 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)*

K193125

Device Name

R2P™ Destination Slender™ Guiding Sheath

Indications for Use *(Describe)*

R2P™ Destination Slender™ Guiding Sheath is indicated for the introduction of interventional and diagnostic devices into the human vasculature through an access site, including but not limited to 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

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

Prepared by:

Liang Lu
Senior Regulatory Affairs Specialist
Terumo Medical Corporation
Tel. (410) 392-7321
Fax (410) 398-6079

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

Terumo Medical Corporation
265 Davidson Avenue, Suite 320
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Registration Number: 2243441

Manufacturer (510(k) Applicant)

Terumo Medical Corporation
950 Elkton Boulevard, Elkton, MD 21921
Registration Number: 1118880

Sterilization Facility

Steris Isomedix Services Inc.
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South Plainfield, NJ 07080
Registration Number: 2246552

Contact Person:

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Date prepared: January 3, 2020

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

Proprietary Name:	R2P™ Destination Slender™ Guiding Sheath
Common Name:	Guiding 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: K171491 – R2P™ Destination Slender™ Guiding Sheath, manufactured by Terumo Medical Corporation, USA

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the R2P™ Destination Slender™ Guiding Sheath, 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 R2P™ Destination Slender™ Guiding Sheath is a low profile guiding sheath designed to perform as a guiding catheter and an introducer sheath. The sheath is coil reinforced, has a radiopaque tip, is hydrophilically coated, and is available in 6Fr with a length of 75cm, 85cm, 95cm, 105cm, 119cm and 149cm. It comes packaged with a dilator and hemostatic valve.

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

R2P™ Destination Slender™ Guiding Sheath is indicated for the introduction of interventional and diagnostic devices into the human vasculature through an access site, including but not limited to the radial artery.

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

The R2P™ Destination Slender™ Guiding Sheath, 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:** R2P™ Destination Slender™ Guiding Sheath (K171491)	**Proposed Device:** R2P™ Destination Slender™ Guiding Sheath
Manufacturer	Terumo Medical Corporation	Same
Intended Use / Indications for Use	R2P™ Destination Slender™ Guiding Sheath is indicated to be used for the introduction of interventional and diagnostic devices in the lower extremities of the peripheral vasculature through an access site, including but not limited to the radial artery.	R2P™ Destination Slender™ Guiding Sheath is indicated for the introduction of interventional and diagnostic devices into the human vasculature through an access site, including but not limited to the radial artery.
Operation Principle	Operated manually or by a manual process	Same
Design / Construction	Sheath, Dilator, Hemostatic Valve with side tube and three-way stopcock	Same
Materials	**Sheath Assembly** Tubing: Inner Layer: PTFE Middle Coil Layer: Stainless Steel Outer Layer: Nylon Radiopaque Tip: Nylon with Tungsten Hydrophilic Coating: Polyvinylpyrrolidone- based coating Hub: Nylon Anti-kink protector: Nylon	**Sheath Assembly** Same
	Dilator Assembly Tubing: Polypropylene Hub: Polypropylene/ /Thermoplastic Elastomer Blend Coating: Silicone Caulking Pin: Stainless steel	**Dilator Assembly** Same
	Cross Cut Valve (CCV) <u>Valve Assembly:</u> Housing: Polypropylene Cap: Polypropylene Luer Lock Collar: Polycarbonate Valve: Silicone Rubber Elastomer Sidetube: polybutadiene Silicone: Non-reactive silicone oil 1000cst	**Cross Cut Valve (CCV)** <u>Valve Assembly:</u> Same

	Side Tube Assembly: Body: Polybutadiene 3Way (3WSC) Stopcock Assembly: Body: Polycarbonate Locking Pin: Polyethylene Cap: Polyethylene and Colorant Handle: Polyethylene and Colorant	Side Tube Assembly: Same 3Way (3WSC) Stopcock Assembly: Same
Package	Unit Pouch Shelf Box Shipping Carton	Same
Specifications	Sheath Size: 6 Fr. Sheath ID/OD (nominal): 6Fr.: 0.087”/0.100” (2.2mm /2.5mm) Sheath Length: 119cm, 149cm Hydrophilic Coating: full effective length Distal Shape: Straight Dilator ID/OD (nominal): 0.039”/0.086” Dilator Extended Length: 5cm	Sheath Size: Same Sheath ID/OD (nominal): Same Sheath Length: **75cm, 85cm, 95cm, 105cm,** 119cm, and 149cm Hydrophilic Coating: Same Distal Shape: Same Dilator ID/OD (nominal): Same Dilator Extended Length: Same
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 R2P™ Destination Slender™ Guiding Sheath 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 provides a list of the performance tests that were performed on the proposed R2P™ Destination Slender™ Guiding Sheath.

Table 5.2: Summary of Performance Testing

Test Item	Reference	Component (Sheath, Dilator, CCV Assembly)
Ovalization	In-house standard	Sheath
Simulated Use and Particulate	FDA Guidance Doc 1608	Sheath, Dilator, CCV
Coating Integrity	FDA Guidance Doc 1608	Sheath
Torque Strength	FDA Guidance Doc 1608	Sheath

The R2P™ Destination Slender™ Guiding Sheath tested met the predetermined acceptance criteria, and results support a determination of substantial equivalence. Based on the results of the performance testing, the proposed R2P™ Destination Slender™ Guiding Sheath demonstrates the substantial equivalence to the predicate device.

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."*

The R2P™ Destination Slender™ Guiding Sheath is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24 hours).

The predicate guiding sheaths (119cm and 149cm) have fulfilled all testing required per ISO 10993-1 and FDA Guidance document "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"

No changes in the materials, design, manufacturing processes, or packaging materials were made from the predicate device. The new additional four (4) shorter guiding sheaths (75cm, 85cm, 95cm, and 105cm) have the same contact nature and duration as the existing predicate guiding sheaths (119cm and 149cm). The predicate guiding sheaths (119cm and 149cm) have higher surface areas, which is the worst-case when compared to the new additional guiding sheaths (75cm, 85cm, 95cm, and 105cm).

The subject device is covered by the previously completed biocompatibility and chemistry testing done on the 149cm guiding sheath. Therefore, the subject devices (75cm, 85cm, 95cm, 105cm, 149cm, and 119cm) are considered to be biocompatible for the intended use and no additional biocompatibility testing is required.

Sterilization

The sterility of the predicate devices (119cm and 149cm) are 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 previously validated utilizing the overkill half cycle approach to provide a Sterility Assurance Level (SAL) of 10^{-6}.

The predicate devices (119cm and 149cm) are limited exposure devices. 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.

The subject devices (75cm, 85cm, 95cm, 105cm, 119cm, and 149cm) have the same configuration, materials of the construct, and manufacturing process as the predicate products; the only change is the length of the device. The manufacturing process will occur in the same manufacturing environment and use the same manufacturing process and materials. The length change to 75cm, 85cm, 95cm, and 105cm, will not affect the efficacy of the current sterilization process and will not create a greater challenge to the cycle than the existing validated process challenge device. Therefore, the subject devices (75cm, 85cm, 95cm, 105cm, 119cm, and 149cm) are covered by the previously completed sterilization validation and no additional sterilization validation is required.

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 R2P™ Destination Slender™ Guiding Sheath, 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: K171491 – R2P™ Destination Slender™ Guiding Sheath, manufactured by Terumo Medical Corporation, USA