October 5, 2017

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

Re: K171491
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: September 6, 2017
Received: September 7, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171491

Device Name
R2P™ Destination Slender™ Guiding Sheath

Indications for Use *(Describe)*
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.

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."

K171491 510(K) SUMMARY

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

Prepared by:

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Prepared for: ***Owner/Operator***
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Date prepared: May 11, 2017

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 are:

- Primary Predicate Device: K052185 – Destination Carotid Guiding Sheath, manufactured by Terumo Medical Corporation, USA
- Reference Device: K161546 – R2P SlenGuide, manufactured by Terumo Corporation

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 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 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.

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 on the table below.

Table 12.1: Summary of Substantial Equivalence

Device Characteristic	**New Device:** R2P™ Destination Slender™ Guiding Sheath	**Primary Predicate:** Destination Carotid Guiding Sheath (K052185)	**Reference Device:** R2P SlenGuide (K161546)
Manufacturer	Terumo Medical Corporation	Terumo Medical Corporation	Terumo Corporation
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.	The Destination® Guiding Sheath is designed to be used for the introduction of interventional and diagnostic devices into the human vasculature including but not limited to the carotid arteries.	The R2P (radial to peripheral) SlenGuide is designed for the introduction of interventional and diagnostic devices into the peripheral vasculature of the lower extremities
Operation Principle	Operated manually or by a manual process;	Same	Same
Design / Construction	Sheath, Dilator, Hemostatic Valve with side tube and three-way stopcock	Same	Guiding Catheter, Inner Guide

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** Tubing: Inner Layer: PTFE Middle Coil Layer: Stainless Steel Outer Layer: Nylon Tip: Nylon Radiopaque Band: Gold Hydrophilic Coating: Polyvinylpyrrolidone-based coating Hub: Nylon	**Guiding Catheter:** Outer layer: Polyamide elastomer (Nylon) Middle Braid Layer: Stainless steel Inner layer: Polytetrafluoroethylene Radiopaque Tip: Polyamide Elastomer (Nylon) with Tungsten Hydrophilic Coating: Dimethyl acrylic amide - glycidyl methacrylate Hub: Polyamide 12 Anti-kink protector: Polyester Elastomer
	Dilator Assembly Tubing: Polypropylene Hub: Polypropylene/ /Thermoplastic Elastomer Blend Coating: Silicone Caulking Pin: Stainless steel	**Dilator Assembly** Same	**Inner Guide:** Shaft: Polyester Elastomer with Tungsten Hub: Polyamide Lock Adaptor: polycarbonate

	Cross Cut Valve Valve Assembly: Housing: Polypropylene Cap: Polypropylene Luer Lock Collar: Polycarbonate Valve: Silicone Rubber Elastomer Sidetube: polybutadiene Silicone: Non-reactive silicone oil 1000cst Side Tube Assembly: Body: Polybutadiene 3Way (3WSC) Stopcock Assembly: Body: Polycarbonate Locking Pin: Polyethylene Cap: Polyethylene and Colorant Handle: Polyethylene and Colorant Lock Adaptor: Polycarbonate	**Cross Cut Valve** Valve Assembly: Same Side Tube Assembly: Same 3Way (3WSC) Stopcock Assembly: Same **Tuohy-Borst Valve** Similar material as Cross Cut Valve	**None**
Package	Unit Pouch Shelf Box Shipping Carton	Unit Pouch Shelf Box Shipping Carton	Unit Pouch Shelf Box Shipping Carton

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: 6-7 Fr. Sheath ID/OD (nominal): 6Fr.: 0.087”/0.111” 7Fr.: 0.100”/0.122” Sheath Length: 80-110cm Hydrophilic Coating: Distal 15cm Distal Shapes: Straight, Angled (40 degrees) Dilator ID/OD (nominal): 6Fr.: 0.045”/0.084” 7Fr.: 0.045”/0.097” Dilator Extended Length: 5cm	Catheter Size: 7Fr I.D.: 2.20 mm (0.087”) O.D.: 2.37 mm (0.093”) Effective lengths: 120cm, 150cm Inner Guide Accepts guide wire diameter: 0.035”
Sterilization	Ethylene Oxide (validated in accordance with ANSI / AAMI / ISO 11135-1 to achieve SAL 10^{-6})	Same	Same
Shelf life	30 months	Same	36 months
Disposable Single Use	Yes	Same	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 5.4: Summary of Performance Testing

Test Item	Reference	Component (Sheath, Dilator, CCV Assembly)
Three-Point Bend	In-house standard	Sheath
Hub Joint Strength	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013	Sheath
Tubing Tensile Strength	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013	Sheath
Tip Tensile Strength	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013	Sheath
Ovalization	In-house standard	Sheath
Lubricity and Durability	In-house standard	Sheath
Uncoated Length	In-house standard	Sheath
Corrosion Resistance	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013	Sheath, Dilator
Gauging	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013 ISO 594-1:1986	Sheath
Liquid Leakage of Luer under Pressure	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013 ISO 594-2:1998	Sheath
Air Leakage	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013 ISO 594-2:1998	Sheath
Separation Force	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013 ISO 594-2:1998	Sheath
Unscrewing Torque	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013 ISO 594-2:1998	Sheath
Ease of Assembly	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013	Sheath

Test Item	Reference	Component (Sheath, Dilator, CCV Assembly)
	ISO 594-2:1998	
Resistance to Overriding	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013 ISO 594-2:1998	Sheath
Stress Cracking	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013 ISO 594-2:1998	Sheath
Simulated Use and Particulate*	FDA Guidance Doc 1608	Sheath, Dilator, CCV
Radiodetectability	ISO 11070:2014 ISO 10555-1:2013	Sheath, Dilator
Visual Inspection of External Surface	ISO 11070:2014 ISO 10555-1:2009 ISO 10555-1:2013	Sheath, Dilator
Sheath Tip Inner Diameter	In-house standard	Sheath
Sheath Hub Inner Diameter	In-house standard	Sheath
Dilator Bump Inner Diameter	In-house standard	Dilator
Outer Diameter Measurement	In-house standard	Sheath, Dilator
Effective Length	In-house standard	Sheath, Dilator
Coating Integrity	FDA Guidance Doc 1608	Sheath
Liquid Leakage of the Sheath	ISO 11070:2014	Sheath
Liquid Leakage Through Hemostasis Valve	ISO 11070:2014	CCV
Torque Strength	FDA Guidance Doc 1608	Sheath
Dilator Tip Inner Diameter	In-house standard	Dilator
Dilator Tip Penetration	In-house standard	Dilator

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 is substantially equivalent.

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 following tests are recommended by FDA and ISO 10993-1 to be performed per this device classification:

1. Cytotoxicity
2. Sensitization
3. Intracutaneous Reactivity
4. Systemic Toxicity (Acute)
5. Pyrogenicity
6. Hemocompatibility
7. Thrombogenicity
8. Complement Activation (Immunology)
9. Physiochemical Testing

Results of the testing demonstrate biocompatibility of the finished R2P™ Destination Slender™ Guiding Sheath.

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}.

R2P™ Destination Slender™ Guiding Sheath is a limited exposure device. 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) 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(s):

- Primary Predicate Device: K052185 – Destination Carotid Guiding Sheath, manufactured by Terumo Medical Corporation, USA
- Reference Device: K161546 – R2P SlenGuide, manufactured by Terumo Corporation