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October 14, 2016

Terumo Medical Corporation
Ms. Monika McDole-Russell
Senior Regulatory Affairs Specialist
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Re: K161546

Trade/Device Name: R2P SlenGuide
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 13, 2016
Received: September 14, 2016

Dear Ms. McDole-Russell:

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 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 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 yours,


Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161546

Device Name

R2P™ SlenGuide™

Indications for Use (Describe)

The R2P (radial to peripheral) SlenGuide is designed for the introduction of interventional and diagnostic devices into the peripheral vasculature of the lower extremities.

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.

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510(K) SUMMARY

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

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Date prepared: October 7, 2016

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

<i>Proprietary Name:</i>	R2P™ SlenGuide™
<i>Common Name:</i>	Guiding Catheter
<i>Classification Name:</i>	Percutaneous Catheter
<i>Classification Panel:</i>	Cardiovascular
<i>Regulation:</i>	21 CFR 870.1250
<i>Product Code:</i>	DQY
<i>Classification:</i>	Class II

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

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

- Predicate Device: K972978 – Vista Brite Tip Guiding Catheters, manufactured by Cordis Corporation.
- Reference Device 1: K142819 – Shuttle-SL Flexor Tuohy-Borst Side-Arm Introducer Set, manufactured by Cook, Inc. (hereinafter referred to as “Flexor Introducer Set”)*
*Flexor Introducer Set (K142819) is presented as a reference predicate for the Inner Guide.
- Reference Device 2: K090040 Radifocus Glidecath/Glidecath XP, manufactured by Terumo Corporation.
* Radifocus Glidecath/Glidecath XP (K090040) is presented as a reference predicate for device length.

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the R2P SlenGuide, manufactured by Ashitaka Factory of Terumo Corporation, for the purposes of establishing substantial equivalence to a legally marketed predicate device.

E. DEVICE DESCRIPTION (807.92(a)(4))***Principle of Operation Technology***

The R2P SlenGuide is operated by manual process.

Design/Construction

The R2P SlenGuide is a single use, ethylene oxide sterilized device that is designed to perform as a guiding catheter for interventional procedures in the peripheral vasculature. It is packaged with a guiding catheter and an inner guide; a description of

each component is provided below.

Guiding Catheter: features a three-layer construction, which consists of a stainless steel mesh sandwiched between an outer layer of polyamide elastomer and an inner layer of polytetrafluoroethylene. The distal end has a hydrophilic coating and contains a “soft-tip,” which is visible under fluoroscopy.

Inner Guide: is an accessory device for the guiding catheter. Its purpose is to help direct the guiding catheter to the lesion, and once achieved, the inner guide is removed, in order to proceed with the interventional procedure. It is comprised of polyester elastomer, and the distal portion is a flexible polyester elastomer, containing tungsten, which is visible under fluoroscopy.

Materials

The materials for the R2P SlenGuide are provided in the table below.

Table 5.1: List of Materials

Name of Component			Raw Material	
Guiding Catheter	Catheter	Outer layer*	Shaft	Polyamide elastomer Pigment
			Distal part	Polyamide elastomer Pigment
				Soft-tip
		Inner layer*		Polytetrafluoroethylene
		Braid†		Stainless steel
		Hub*		Polyamide 12 Pigment
	Hydrophilic polymer coating*		Dimethyl acrylic amide - glycidyl methacrylate copolymer	
	Anti-kink protector		Polyester elastomer Pigment	
	Inner Guide	Shaft*	Distal part	Polyester elastomer Tungsten
			Proximal part	Polyester elastomer
Hub*		Polyamide		
Lock adaptor		Polycarbonate		
Adhesive		Cyanoacrylate		

*Blood contacting material.

†Soft-tip is not braided.

Specifications

The specifications for the R2P SlenGuide are provided in the table below.

Table 5.2: R2P SlenGuide Specifications

Part	Specification
Catheter Size	7Fr.
Catheter ID/OD	2.20 mm/2.37 mm
Catheter Effective Lengths*	120 and 150 cm
Inner Guide ID/OD	1.15 mm/2.10 mm
Inner Guide Extended Length†	30 mm
Accepts Guide Wire Diameter	0.035"

*The length from the proximal anti-kink protector to the guiding catheter distal tip.

†The length that the inner guide extends past the guiding catheter's tip.

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

The R2P (radial to peripheral) SlenGuide is designed for the introduction of interventional and diagnostic devices into the peripheral vasculature of the lower extremities.

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

The R2P SlenGuide, subject of this Traditional 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to:

- Predicate Device: K972978 – Vista Brite Tip Guiding Catheters, manufactured by Cordis Corporation.
- Reference Device 1: K142819 – Flexor Introducer Set*, manufactured by Cook, Inc.
*Flexor Introducer Set (K142819) is presented as a reference predicate for the Inner Guide.
- Reference Device 2: K090040 Radifocus Glidecath/Glidecath XP*, manufactured by Terumo Corporation.
* Radifocus Glidecath/Glidecath XP (K090040) is presented as a reference predicate for device length.

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

Table 5.3: Summary of Comparative Information

Device Characteristic		New Device: Guiding Catheter of R2P SlenGuide	Predicate Device: Vista Brite Tip Guiding Catheters (K972978)*	Reference Device 1: Flexor Introducer Set (K142819)*	Reference Device 2: Radifocus Glidecath or Glidecath XP (K090040)
Manufacturer		Terumo Corporation	Cordis Corporation	Cook, Inc.	Terumo Corporation
Intended Use/Indication for Use		The R2P (radial to peripheral) SlenGuide is designed for the introduction of interventional and diagnostic devices into the peripheral vasculature of the lower extremities	The guiding catheter is intended for use for intravascular introduction of interventional / diagnostic devices into the coronary or peripheral vascular systems	Flexor Introducers and Guiding Sheaths are intended to introduce therapeutic or diagnostic devices into the vasculature, excluding coronary and neuro vasculature	The Radifocus Glidecath (or Radifocus Glidecath XP) is intended for use in angiographic procedures. It delivers radiopaque media and therapeutic agents to selected sites in the vascular system. It is also used to lead a guide wire or catheter into the target site.
Operation Principle		Manual	same	same	same
Design/ Construction	Guiding Catheter	Single lumen catheter, stainless steel braid wire, catheter, radiopaque tip, and hub	same	N/A	Single lumen catheter, stainless steel braid wire, catheter containing radiopaque material(tungsten or barium sulfate) and hub
	Inner Guide	Made by plastic materials, featuring a distal taper that allows for smooth transition with the appropriately sized guide wire	N/A	same	N/A

Device Characteristic		New Device: Guiding Catheter of R2P SlenGuide	Predicate Device: Vista Brite Tip Guiding Catheters (K972978)*	Reference Device 1: Flexor Introducer Set (K142819)*	Reference Device 2: Radifocus Glidecath or Glidecath XP (K090040)
<i>Materials</i>	<i>Guiding Catheter</i>	<ul style="list-style-type: none"> Outer layer: Polyamide elastomer (Nylon) Braid: Stainless steel Inner layer: Polytetrafluoroethylene 	same	N/A	
	<i>Inner Guide</i>	<ul style="list-style-type: none"> Shaft: Polyester elastomer 	N/A	<ul style="list-style-type: none"> Shaft: Polyamide elastomer (Nylon) or Polyethylene 	N/A
<i>Package</i>		<ul style="list-style-type: none"> Individual package on which the product label and the peel-off labels are attached 1 unit per package 	same	same	same
<i>Specifications</i>	<i>Guiding Catheter</i>	<ul style="list-style-type: none"> Effective lengths: 120 cm, 150 cm French size: 7Fr O.D.: 2.37 mm I.D.: 2.20 mm (0.087") 	<ul style="list-style-type: none"> Effective lengths: 55 cm, 90 cm, 95 cm French size: 7Fr O.D.: Soft tip: 2.30 mm I.D.: 2.0 mm (0.078") 	N/A	<ul style="list-style-type: none"> Effective lengths: 30 - 150cm French size: 5Fr, 4Fr O.D.: 5Fr 1.70 mm 4Fr 1.40mm I.D.: 5Fr 1.22mm(Double braided) 1.12 mm(Single braided) 4Fr 1.05 mm

Device Characteristic		New Device: Guiding Catheter of R2P SlenGuide	Predicate Device: Vista Brite Tip Guiding Catheters (K972978)*	Reference Device 1: Flexor Introducer Set (K142819)*	Reference Device 2: Radifocus Glidecath or Glidecath XP (K090040)
	<i>Inner Guide</i>	<ul style="list-style-type: none"> Accepts guide wire diameter: 0.035" 	N/A	<ul style="list-style-type: none"> Accepts guide wire diameter: 0.018", 0.035", and 0.038" 	N/A
<i>Sterilization</i>		Ethylene oxide	same	same	same

*Based on publicly available information on the devices.

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

Performance Testing

Performance testing was conducted to ensure that the R2P SlenGuide met the applicable design and performance requirements throughout its shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. With the exception of the Radiodetectability¹ and Cleanliness tests², the following performance tests were performed on non-aged and accelerated aged samples. The following tables provide a list of performance tests that were performed on the R2P SlenGuide.

Table 5.4: Summary of Performance Testing – Guiding Catheter

Component	Test	Standard	Test Method
Guiding Catheter	Radio-detectability	ISO 10555-1:2013 Section 4.2, ASTM F640-12	Test samples using X-ray equipment, that are tested according to ASTM F640-12
	Surface quality	ISO 10555-1:2013 Section 4.4	Check external surfaces of samples with a magnifier (x 2.5 times or more)
	Peak tensile force	ISO 10555-1:2013 Section 4.6 VIII.A.7 of FDA Guidance ³	Using an autograph, measure peak tensile strength of samples
	Freedom from leakage	ISO 10555-1:2013 Section 4.7	Using a syringe filled with water, apply and maintain pressure to the catheter, and then inspect for liquid and air leakage
	Hub performance	ISO 10555-1:2013 Section 4.8 ISO 594-2: 1998	Test hubs for gauging, liquid leakage, air leakage, separation force, unscrewing torque, ease of assembly, resistance to overriding, and stress cracking
	Distal tip appearance	ISO 10555-1:2013 Section 4.12	Check physical appearance of distal tip with a microscope (x 10 times or more)
	Particulate evaluation	VIII.A.13 of FDA Guidance ³ USP <788> In-house Standard	Slide samples into an apparatus filled with purified water, and measure/evaluate residual particles

¹ Only non-aged sample was tested since the amount of contrast media contained in the product would not change over time.

² Only non-aged sample was tested since the particulates inside the catheter lumen would not increase over time.

³ *Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters, September 8, 2010.*

Component	Test	Standard	Test Method
	Torque Strength	VIII.A.10 of FDA Guidance In-house Standard ³	Confirm R2P Slenguide has appropriate torque strength by measuring the rotation of the catheter, when twisting off
	Coating lubricity	VIII.A.12 of FDA Guidance ³ In-house Standard	After the particulate evaluation test, visually evaluate coating under magnification. Then, after pushing and pulling samples in an apparatus, confirm coating lubricity by measuring sliding forces
	Evaluation of flexibility and kink resistance	VIII.A.9 of FDA Guidance ³ In-house Standard	Wind samples around mandrels, until the samples have kinked, and record mandrel size that caused samples to kink
	Distal tip flexibility	In-house Standard	Measure tip force when samples are pushed by an apparatus
	Kink condition	In-house Standard	Kink the samples, and visually inspect with a magnifying glass
	Flexural rigidity	In-house Standard	Samples are set on an apparatus, and maximum force is applied, in order to measure shaft strength
	Distal tip strength	VIII.A.8 of FDA Guidance ³ In-house Standard	Samples are clamped and pulled to measure tensile strength
	Cleanliness	In-house Standard	Water is injected into the samples and is visually inspected for foreign matter
	Product dimensions	In-house Standard	Measure by inner and outer diameter, effective length, and extended length

Table 5.5: Summary of Performance Testing – Inner Guide

Component	Test	Standard	Test Method
Inner Guide	Radio-detectability	ISO 10555-1:2013 Section 4.2 ASTM F640-12	Test samples using X-ray equipment, when tested according to ASTM F640-12
	Surface quality	ISO 10555-1:2013 Section 4.4	Check external surfaces of samples with a magnifier (x 2.5 times or more)
	Peak tensile force	ISO 10555-1:2013 Section 4.6 VIII.A.7 of FDA Guidance ³	Using an autograph, measure peak tensile strength of samples
	Freedom from leakage	ISO 10555-1:2013 Section 4.7	Using a syringe filled with water, apply and maintain pressure to the catheter, and then inspect for liquid and air leakage
	Distal tip appearance	ISO 10555-1:2013 Section 4.12	Check physical appearance of distal tip with a microscope (x 10 times or more)

	Flexural rigidity	In-house Standard	Samples are set on an apparatus, and maximum force is applied, in order to measure shaft strength
	Cleanliness	In-house Standard	Water is injected into the samples and is visually inspected for foreign matter
	Product dimensions	In-house Standard	Measure by inner and outer diameter, effective length, and extended length

Performance testing met the predetermined acceptance criteria and results support a determination of substantial equivalence.

Biocompatibility

In accordance with ISO 10993-1, the R2P SlenGuide is classified as: Externally Communicating Device, Circulating Blood, Limited Contact (<24 hours). The finished device's patient contacting parts were tested in accordance with the tests recommended in the FDA *General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"* and *Draft Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."* Screening tests were performed on accelerated aged devices to show that biocompatibility is maintained throughout the shelf life of the product. The table below provides a list of biocompatibility tests conducted on the R2P SlenGuide.

Table 5.6: Summary of ISO 10993 Biocompatibility Testing

Non-aged, sterile, whole device
Cytotoxicity
Sensitization
Intracutaneous Reactivity
Acute Systemic Toxicity
Pyrogenicity
Hemolysis
Thrombogenicity
Complement Activation (Immunology)
Physicochemical Profile (Physicochemical and FT-IR)
Accelerated-aged (3 years), sterile, whole device
Cytotoxicity
Hemolysis
Physicochemical Profile (Physicochemical and FT-IR)

Results of the testing demonstrate that the device is biocompatible throughout the shelf life of the product.

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*, to provide a Sterility Assurance Level (SAL) of 10^{-6} .

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 SlenGuide, subject of this 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to:

- Predicate Device: K972978 – Vista Brite Tip Guiding Catheters, manufactured by Cordis Corporation.