July 27, 2023

Terumo Medical Corporation
Sandeep Chiplonkar
Regulatory Affairs Specialist II
950 Elkton Blvd
Elkton, Maryland 21921

Re: K231044
Trade/Device Name: R2P Navicross
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 11, 2023
Received: April 12, 2023

Dear Sandeep Chiplonkar:

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,

Samuel G. Raben -S

for Lydia Glaw
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231044

Device Name
R2P NAVICROSS

Indications for Use *(Describe)*
R2P NaviCross is indicated to guide and support a guidewire during access of the peripheral vasculature through an access site, including but not limited to the radial artery, allow for wire exchanges, and provide a conduit for the delivery of saline or diagnostic contrast agents.

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 summary of 510(k) substantial equivalence information in accordance with the requirements of 21 CFR 807.92.

Section Contents

510(K) SUMMARY

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

Prepared by: Sandeep Chiplonkar
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Date Prepared: April 11, 2023

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

Proprietary Name:	R2P NAVICROSS
Common Name:	Support Catheter
Classification Name:	Catheter, Percutaneous
Classification Panel:	Cardiovascular
Regulation:	21 CFR 870.1250
Product Code:	DQY
Classification:	Class II

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

The legally marketed device to which substantial equivalence is claimed is:

Predicate Device:

- K110540, NaviCross ™, Terumo Support Catheter, manufactured by Ashitaka Factory of Terumo Corporation

Reference Device(s):

- K183000 – ViperCath™ XC Peripheral Exchange Catheter
- K171491 – R2P Destination Slender Guiding Sheath

D. REASON FOR 510(k) SUBMISSION

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

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

Principle of Operation Technology

R2P NaviCross submitted in this 510(k) and its predicate (K110540) are operated by a manual process.

Design/Construction

R2P NaviCross is a low-profile, 4.5Fr, 200cm length catheter. It is intended to guide and support a 0.035" or smaller guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents. The catheter is ethylene oxide sterilized for single use only.

The catheter features a three-layer construction, consisting of a stainless steel double braid mesh sandwiched between an outer and inner layer of polyester elastomer. The mesh is embedded within the catheter wall the entire length of the catheter with the exception of the distal tip. The distal tip is comprised of a polyester elastomer and is offered in both a straight and an angled tip shape. The catheter features three embedded radiopaque markers, one platinum alloy marker located 2mm from the distal tip, and two gold alloy markers. The first gold alloy marker is located 40mm from the distal edge of the platinum alloy marker, and the second gold marker is located 60mm from the distal edge of the first gold marker. There are also two proximal depth markers (pigment), located at 120cm and 150cm, which are there to help with procedural efficiency and minimize the use of fluoroscopy. The distal 40cm portion of the device has a hydrophilic coating. The catheter body is attached to a polyamide hub and a strain relief that contains a polyether block amide (PEBA with colorant and HLS).

The device is offered in an effective length of 200cm. French size and shaft inner diameter are as follows:

French Size	Shaft Inner Diameter (mm)	Shaft Outer Diameter (mm)
4.5Fr	1.05mm +0/- 0.02mm	1.48 ± 0.01mm

Materials

The materials for R2P NaviCross are provided in Table 5.1.

Table 5.1: List of Materials

No.	Name of Component			Raw Material
1*	Catheter	Shaft	Outer layer	Polyester elastomer
2			Mesh Braid	Stainless steel
3*			Inner Layer	Polyester elastomer
4*		Distal tip***		Polyester elastomer
5		Radiopaque Markers	Distal tip (1)	Platinum alloy
			Embedded (2)	Gold alloy
6*		Proximal depth markers (2) (non-radiopaque)		Pigment (White ink)
7*	Hydrophilic polymer coating			Dimethylacrylamide Glycidylmethacrylate - copolymer
8**	Quick Drying Glue			Acrylated Urethane
9**	Hub			Polyamide
10**	Strain Relief			Polyether block amide (PEBA) with colorant and HLS

*Blood contacting material, ** Blood Path Indirect, ***Distal tip is not braided.

Specifications

The specifications for R2P NaviCross are provided in Table 5.2.

Table 5.2: R2P NaviCross Specifications

Part	Specification
Catheter French Size	4.5 Fr.
Catheter ID/OD	1.05 +0/-0.02mm /1.48 ± 0.01mm
*Catheter Effective Lengths	200cm -0/+3cm
Hydrophilic Coating Length	Distal 40 ± 3cm
Maximum guide wire outer diameter	0.035”

*The length from the proximal strain relief to the catheter distal tip.

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

R2P NaviCross is indicated to guide and support a guidewire during access of the peripheral vasculature through an access site, including but not limited to the radial artery, allow for wire exchanges, and provide a conduit for the delivery of saline or diagnostic contrast agents.

The intended use is equivalent to the predicate device (K110540).

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

R2P NaviCross, the subject of this Traditional 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate, K110540, NaviCross ™, Terumo Support Catheter, manufactured by Ashitaka Factory of Terumo Corporation.

In addition to the above listed predicate, Terumo Medical Corporation has identified the following reference device(s). These are market leading devices with the same intended use, basic design, and similar indications for use as the subject device. Since these devices are frequently used in clinical practice, Terumo felt that they were appropriate to use as references.

1. Cardiovascular Systems, Inc. (K183000) – ViperCath™ XC Peripheral Exchange Catheter
2. Terumo Medical Corporation (K171491) – R2P Destination Slender Guiding Sheath

A comparison of the technological characteristics is summarized in **Table 5.3.**

Table 5.3: Summary of Comparative Information

Device Characteristic	Subject Device: R2P NAVICROSS	Predicate Device: NAVICROSS™ Terumo Support Catheter (K110540)	Reference Device #1: ViperCath™ XC Peripheral Exchange Catheter (K183000)	Reference Device #2: R2P Destination Slender Guiding Sheath (K171491)
Manufacturer	Terumo Medical Corporation, USA	Ashitaka Factory of Terumo Corporation	Cardiovascular Systems, Inc.	Terumo Medical Corporation, USA
Intended Use	R2P NaviCross is intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.	Same.	Same.	Same.
Indications for Use	R2P NaviCross is indicated to guide and support a guidewire during access of the peripheral vasculature through an access site, including but not limited to the radial artery, allow for wire exchanges, and provide a conduit for the delivery of saline or diagnostic contrast agents.	Terumo Support Catheters are intended to guide and support a guidewire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.	The ViperCath™ XC Peripheral Exchange Catheter is intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.	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.
Operation Principle	Manual	Same	Same	Same
Design/Construction	Three-layer construction catheter shaft with hydrophilic coating, distal tip and hub.	Same	Information not publicly available.	Sheath, Dilator, Hemostatic Valve with side tube and three-way stopcock

Device Characteristic	Subject Device: R2P NAVICROSS	Predicate Device: NAVICROSS™ Terumo Support Catheter (K110540)	Reference Device #1: ViperCath™ XC Peripheral Exchange Catheter (K183000)	Reference Device #2: R2P Destination Slender Guiding Sheath (K171491)
Materials	• Catheter shaft • Outer layer*: Polyester elastomer/tungsten • Braid: Stainless steel • Inner layer*: Polyester elastomer/Tungsten • Hydrophilic coating*: Dimethylacrylamide Glycidylmethacrylate-copolymer • Three radiopaque markers: 1: Platinum Alloy, 2: Gold • Two Proximal depth markers* (non-radiopaque): Pigment • Hub**: Polyamide • Strain Relief**: Polyether block amide (PEBA), with colorant and HLS • Adhesive**: Acrylated Urethane *: blood contacting material **: blood path indirect	• Catheter shaft - Outer layer*: Polyester elastomer/tungsten - Mesh braid: Stainless steel - Inner layer*: Polyester elastomer/tungsten - Hydrophilic coating*: Dimethyl acrylamide-glycidyl methacrylate copolymer - Three radiopaque markers*: Platinum alloy • Hub*: Polyamide • Anti-kink protector: Polyester elastomer w/pigment • Adhesive: Cyanoacrylate *: blood contacting material	Information not publicly available.	**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 **Dilator Assembly** Tubing: Polypropylene Hub: Polypropylene/ /Thermoplastic Elastomer Blend Coating: Silicone Caulking Pin: Stainless steel **Cross Cut Valve** Valve Assembly: Housing: Polypropylene Cap: Polypropylene Luer Lock Collar:

Device Characteristic	Subject Device: R2P NAVICROSS	Predicate Device: NAVICROSS™ Terumo Support Catheter (K110540)	Reference Device #1: ViperCath™ XC Peripheral Exchange Catheter (K183000)	Reference Device #2: R2P Destination Slender Guiding Sheath (K171491)
				Polycarbonate Valve: Silicone Rubber Elastomer Sidetube: polybutadiene Silicone: Non-reactive silicone oil 1000cst <u>Side Tube Assembly:</u> Body: Polybutadiene <u>3Way (3WSC) Stopcock Assembly:</u> Body: Polycarbonate Locking Pin: Polyethylene Cap: Polyethylene and Colorant Handle: Polyethylene and Colorant
Package	• Individual package on which the product label and the peel-off labels are attached • 1 unit per package	Same	Same	Unit Pouch Shelf Box Shipping Carton
Specifications	• Effective length(s): 200cm • French size: 4.5Fr • O.D.: 1.48 mm	• Effective length(s): 65, 90, 135 and 150 cm • French size: 4Fr • O.D.: 1.39 mm	• Effective length(s): 200cm • French size: 5Fr • O.D.: Unknown	• Sheath Size: 6 Fr. Sheath ID/OD (nominal): 6Fr.: 0.087”/0.100” (2.2mm /2.5mm)

Device Characteristic	Subject Device: R2P NAVICROSS	Predicate Device: NAVICROSS™ Terumo Support Catheter (K110540)	Reference Device #1: ViperCath™ XC Peripheral Exchange Catheter (K183000)	Reference Device #2: R2P Destination Slender Guiding Sheath (K171491)
	• I.D.: 1.05 mm • Maximum guidewire outer diameter: 0.035” • Distal tip shape: straight/angled • Maximum injection pressure: 600 psi	• I.D.: 1.05 mm • Maximum guidewire outer diameter: 0.035” • Distal tip shape: straight/angled • Maximum injection pressure: 750 psi	• I.D.: Unknown • Maximum guidewire outer diameter: 0.035” • Distal tip shape: straight/angled • Maximum injection pressure: 600 psi	• Sheath Length: 119cm, 149cm • Hydrophilic Coating: full effective length Distal Shape: Straight • Dilator ID/OD (nominal): 0.039”/0.086” • Dilator Extended Length: 5cm
Sterilization	Ethylene oxide	Same	Same	Same
Shelf Life	*6 months	36 months	Unknown	30 months

*This 510(k) is being submitted with T=6AA testing completed. The subject device will have an ultimate shelf life of 36 months, equivalent to the predicate device.

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

Performance

Performance testing was conducted to ensure that the R2P NaviCross is as substantially equivalent to the predicate device throughout the shelf life, verify conformity to the applicable external and internal standards, and demonstrate substantial equivalence to the predicate device. With the exception of the Radiodetectability test, the following performance tests were performed on both non-aged and accelerated aged samples. Table 5.4 provides a list of performance tests that were performed on R2P NaviCross.

Table 5.4: Summary of Performance Testing

Test Item
Depth Marker Length
Effective Length
Wire Exchange Force
Wire Support
Trackability
Lesion Crossing Force
Torque Response
Flow Rate
Low Pressure Hub Leakage
Aspiration Hub Leakage
Torque Strength
Resistance to Separation from Axial Load
Resistance to Separation from Unscrewing
Resistance to Overriding
Radiodetectability
Lubricity Testing
Hub to Tubing Tensile Strength
Braided to Unbraided Tubing Tensile Strength
Simulated Use and Particulate Testing
Coating Integrity
Leakage Atmospheric
Leakage Sub-Atmospheric
Stress Cracking

Test Item
Catheter OD (Braided/Unbraided
Burst Pressure
Flexibility and Kink Testing

Performance testing for t=0 and t=6AA (accelerated age), met the predetermined acceptance criteria and is acceptable for clinical use throughout the shelf life of 6 months. Testing for t=36AA is currently in progress.

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".*

In accordance with ISO 10993-1, R2P NaviCross is classified as an Externally Communicating Device with Limited Contact (≤24 hours) with Circulating Blood.

Table 5.6 provides a list of biocompatibility testing conducted on R2P NaviCross.

Table 5.6: Summary of ISO 10993 Biocompatibility Testing

Non-aged, sterile, whole device	Applicable Standard(s)
Chemical Characterization	ISO 10993-18:2020, USP <661>
Cytotoxicity	EN ISO 10993-5:2009
Sensitization	ISO 10993-10:2021
Irritation or Intracutaneous Reactivity	ISO 10993-23:2021
Material Mediated Pyrogenicity	ISO 10993-11:2017, USP <151> Pyrogen Test
Acute Systemic Toxicity	ISO 10993-11:2017
Hemocompatibility	ISO 10993-4:2017

Results of the testing demonstrate biocompatibility of the finished R2P NaviCross.

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 NaviCross 035 is a limited exposure device. After 24 hours of heated aeration, the level of residual EO and ECH do not exceed an average daily dose of 4mg and 9mg respectively, per EN ISO 10993-7.

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, R2P NaviCross, subject of this traditional 510(k), is substantially equivalent in its intended use, technology/principal of operation, materials, and performance to the predicate device (K110540) – NaviCross ™, Terumo Support Catheter, manufactured by Ashitaka Factory of Terumo Corporation.

TMC contends that the differences in indications for use from the subject device and predicate and reference devices does not alter the **intended use** of the devices.