March 29, 2018

Terumo Medical Corporation
Ms. Yuko Watanabe
Sr. Regulatory Affairs Specialist
265 Davidson Ave., Suite 320
Somerset, New Jersey 08873

Re: K173799
Trade/Device Name: NaviCross 0.018"
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 16, 2018
Received: March 16, 2018

Dear Ms. Watanabe:

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 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)*
K173799

Device Name
NaviCross 0.018"

Indications for Use *(Describe)*
The NaviCross 0.018" is intended to guide and support a guide wire during access of the peripheral vasculature, 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.

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: Yuko Watanabe
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Date prepared: December 13th, 2017

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

Proprietary Name:	NaviCross 0.018”
Common Name:	Support Catheter
Classification Name:	Percutaneous Catheter
Classification Panel:	Cardiovascular
Regulation:	21 CFR 870.1250
Product Code:	DQY
Classification:	Class II

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

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

Predicate Device: K110540 – TERUMO SUPPORT CATHETER, manufactured by Ashitaka Factory of Terumo Corporation.

Reference Devices:

1. K160884: CXI 0.018” support catheter, Cook, Inc.
2. K033678: Quick-Cross 0.018” support catheter, Spectranetics, Inc.
3. K122394: Rubicon 0.018” support catheter, Boston Scientific Corp.

D. REASON FOR 510(k) SUBMISSION

This traditional 510(k) is being submitted for the NaviCross 0.018”, which will be a line extension of the currently marketed NaviCross 0.035” (K110540, cleared under the name “Terumo Support Catheter”), 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 NaviCross 0.018” submitted in this 510(k) and its predicate (K110540) are operated by a manual process.

Design/Construction

The NaviCross 0.018” is a single use, ethylene oxide sterilized device that is intended to guide and support a guide wire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

NaviCross 0.018” features a three-layer construction, which consists of a stainless steel mesh braid sandwiched between an outer layer of polyamide and an inner layer of polytetrafluoroethylene. It has a distal tip that is comprised of a polyamide. It also has a hydrophilic coating over the distal 40 cm of the catheter.

The device is offered in effective lengths of 65, 90, 135 and 150 cm. French size and shaft inner diameter are as follows:

French Size	Shaft Inner Diameter (mm)
2.6Fr	0.55 ± 0.02

Materials

The materials for the NaviCross 0.018” are provided in the table below.

Table 5.1: List of Materials

No.	Name of Component			Raw material
1*	Catheter	Shaft	Outer layer	Polyamide
				Pigment
2			Braid†	Stainless steel
3*			Inner layer	Polytetrafluoroethylene
4*		Distal tip†		Polyamide
				Pigment
5		Radiopaque marker		Tungsten
6*	Hydrophilic polymer coating			Dimethyl acrylamide – glycidyl methacrylate copolymer
7	Quick-drying glue			Cyanoacrylate
8*	Hub			Polyamide
9	Anti-kink protector			Polyester elastomer
				Pigment

*Blood contacting material.

†Distal-tip is not braided.

Specifications

The specifications for the NaviCross 0.018” are provided in the table below.

Table 5.2: NaviCross 0.018” Specifications

Part	Specification
Catheter Size	2.6 Fr.
Catheter ID/OD	0.55 ± 0.02 mm/0.85 ± 0.03 mm
Catheter Effective Lengths*	65 ± 1.5 cm, 90 ± 1.5 cm, 135 ± 1.5 cm, 150 ± 1.5 cm
Hydrophilic Coating Length	Distal 40 ± 3cm
Maximum guidewire outer diameter	0.018”

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

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

The NaviCross 0.018" is intended to guide and support a guide wire during access of the peripheral vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.

The indications for use are equivalent to the predicate (K110540).

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

The NaviCross 0.018", the subject of this Traditional 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate, K110540 – TERUMO SUPPORT CATHETER, manufactured by Ashitaka Factory of Terumo Corporation.

In addition to the above-listed primary predicate, Terumo has identified the following reference devices. These are market leading devices with the same intended use and basic design as the subject device. Because these devices are frequently used in clinical practice, Terumo felt it was appropriate to use them as references when setting the acceptance criteria for NaviCross 0.018” performance testing.

1. Cook Inc. CXI 0.018” support catheter (K160884)
2. Spectranetics, Inc. Quick-Cross 0.018” support catheter (K033678)
3. Boston Scientific Corp. Rubicon 0.018” support catheter (K122394)

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

Table 5.3: Summary of Comparative Information

Device Characteristic	Subject Device: NaviCross 0.018”	Predicate Device: TERUMO SUPPORT CATHETER (NaviCross 0.035”) (K110540)	Reference Device #1: CXI 0.018” support catheter (K160884)	Reference Device #2: Quick-Cross 0.018” support catheter (K033678)	Reference Device #3: Rubicon 0.018” support catheter (K122394)
Manufacturer	Ashitaka Factory of Terumo Corporation	Same	Cook Inc.	Spectranetics, Inc.	Boston Scientific Corp.
Intended Use /Indications for Use	It is intended to guide and support a guide wire during access of the **peripheral** vasculature, allow for wire exchanges and provide a conduit for the delivery of saline or diagnostic contrast agents.	It 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.	It is intended for use in small vessel or superselective anatomy for diagnostic and interventional procedures, including peripheral use.	It is designed for use in the vascular system. The catheters are intended to support a guidewire during access of the vasculature, allow for exchange of guidewires, and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.	It is intended to facilitate placement and support of guidewires and other Interventional devices within the peripheral vasculature and to allow for exchange of guidewires, and provide a conduit for the delivery of saline or contrast solutions.
Operation Principle	Manual	Same	Same	Same	Same
Design/ Construction	Three-layer construction catheter shaft with hydrophilic coating, distal tip and hub	Same	Multi layers with hydrophilic coating, distal tip and hub	One layer with hydrophilic coating, distal tip and hub	Multi layers with hydrophilic coating, distal tip and hub

Device Characteristic	Subject Device: NaviCross 0.018"	Predicate Device: TERUMO SUPPORT CATHETER (NaviCross 0.035") (K110540)	Reference Device #1: CXI 0.018" support catheter (K160884)	Reference Device #2: Quick-Cross 0.018" support catheter (K033678)	Reference Device #3: Rubicon 0.018" support catheter (K122394)
Materials	• Catheter shaft - Outer layer*: Polyamide w/ pigment - Mesh braid: Stainless steel - Inner layer*: Polytetrafluoroethylene - Hydrophilic coating*: Dimethyl acrylamide-glycidyl methacrylate copolymer - Three radiopaque markers: Tungsten • Distal Tip*: Polyamide w/ pigment • Hub*: Polyamide • Anti-kink protector: Polyester elastomer w/ pigment • Adhesive: Cyanoacrylate *: blood contacting material	• 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.	Information not publicly available.	Information not publicly available.

Device Characteristic	Subject Device: NaviCross 0.018”	Predicate Device: TERUMO SUPPORT CATHETER (NaviCross 0.035”) (K110540)	Reference Device #1: CXI 0.018” support catheter (K160884)	Reference Device #2: Quick-Cross 0.018” support catheter (K033678)	Reference Device #3: Rubicon 0.018” support catheter (K122394)
Package	• Individual package on which the product label and the peel-off labels are attached • 1 unit per package	Same	Same	Same	Same
Specifications	• Effective lengths: 65, 90, 135 and 150 cm • French size: 2.6Fr (0.85 mm) • O.D.: 0.85 mm • I.D.: 0.55 mm • Maximum guidewire outer diameter: 0.018” • Distal tip shape: straight/angled • Maximum injection pressure: 300 psi	• Effective lengths: 65, 90, 135 and 150 cm • French size: 4Fr (1.39 mm) • O.D.: 1.39 mm • I.D.:1.05 mm • Maximum guidewire outer diameter: 0.035” • Distal tip shape: straight/angled • Maximum injection pressure: 750 psi	• 90, 150 cm • 2.6 Fr • O.D.: 0.87 mm • I.D.: unknown • Same (0.018”) • Same (straight/angled) • 1200 psi	• 90, 135 and 150 cm • 3.4 Fr • O.D.: 1.12 mm (Proximal shaft) • I.D.: unknown • Same (0.018”) • Straight only • Same (300 psi)	• 90, 135 and 150 cm • 4.0 Fr • O.D.: 1.35 mm (Proximal shaft) • I.D.: unknown • Same (0.018”) • Straight only • Same (300 psi)
Sterilization	Ethylene oxide	Same	Same	Radiation	Same
Shelf life	36 months	Same	Unknown	Unknown	Unknown

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

Performance Testing

Performance testing was conducted to ensure the safety and effectiveness of the NaviCross 0.018” 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 Radio-detectability[1] test, the following performance tests were performed on non-aged and accelerated aged samples. The following table provides a list of performance tests that were performed on the NaviCross 0.018”.

Table 5.4: Summary of Performance Testing

Test Item
Radio-detectability
Surface
Peak tensile force
Freedom from leakage
Power injection
Distal tip
Fluid leakage (Hub)
Sub-atmospheric pressure air leakage (Hub)
Stress cracking (Hub)
Resistance to separation from axial load (Hub)
Resistance to separation from unscrewing (Hub)
Resistance to overriding (Hub)
Particulate evaluation
Coating integrity
Torque strength
Distal tip strength
Flow rate
Product dimension
Bending stiffness of catheter shaft
Flexibility and kink test
Torque transmission property
Interior sliding characteristics
Exterior sliding characteristics
Wire support characteristics
Simulated Use - Reachability
Simulated Use – Usability Test

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

Performance testing met the predetermined acceptance criteria and is acceptable for clinical use throughout its shelf life.

Biocompatibility

In accordance with ISO 10993-1, the NaviCross 0.018" 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 *Guidance for Industry and Food and Drug Administration Staff - Use of International Standard ISO-10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* Screening tests were performed on accelerated aged devices to show that the biocompatibility is maintained throughout the shelf life of the product. The table below provides a list of biocompatibility tests conducted on the NaviCross 0.018".

Table 5.5: 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 NaviCross 0.018”, the subject of this 510(k), is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the predicate, K110540 – TERUMO SUPPORT CATHETER, manufactured by Ashitaka Factory of Terumo Corporation.