November 21, 2017

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

Re: K172995
Trade/Device Name: Destination Carotid Guiding Sheath, Destination Peripheral Guiding Sheath, Destination Renal Guiding Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: September 19, 2017
Received: September 27, 2017

Dear Mr. 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.

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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172995

Device Name
Destination® Carotid Guiding Sheath
Destination® Peripheral Guiding Sheath
Destination® Renal Guiding Sheath

Indications for Use *(Describe)*

The Destination® Carotid 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 Destination® Peripheral Guiding Sheath is designed to be used for the introduction of interventional and diagnostic devices into the human vasculature, including but not limited to lower extremity access via a contralateral approach.

The Destination® Renal Guiding Sheath is intended for the introduction of interventional and diagnostic devices into the human vasculature including but not limited to the renal arteries.

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:

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Prepared for: ***Owner/Operator***
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Date prepared: July 20, 2017

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

Proprietary Name:	Destination® Carotid Guiding Sheath Destination® Peripheral Guiding Sheath Destination® Renal 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:

- Predicate Device: K052185 – Destination® Carotid Guiding Sheath, manufactured by Terumo Medical Corporation
- Predicate Device: K091329 – Destination® Peripheral Guiding Sheath, manufactured by Terumo Medical Corporation
- Predicate Device: K081045 – Destination® Renal Guiding Sheath, manufactured by Terumo Medical Corporation

The primary predicate device is K052185.

D. REASON FOR 510(k) SUBMISSION

This premarket notification (510(k)) is being submitted for the Destination® 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 Destination® Guiding Sheath is designed to perform as a guiding catheter and an introducer sheath. The Destination® Guiding Sheath is a 3-layer tubing with a Stainless-Steel coil reinforcement sandwiched between layers of PTFE Teflon and Nylon Pebax, a hemostatic valve at the proximal end, a radiopaque marker near the distal end, and a hydrophilic coating on the distal portion of the tubing of varying lengths based on the product code. The sheath is available in multiple French sizes, useable lengths and distal shape configurations. The Destination® Guiding Sheaths are packaged with the following components: a Sheath, a Dilator, a Hemostatic Valve, and a Dilator Retaining Clip (only available with codes that contain the Tuohy-borst valve).

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

The Destination® Carotid 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 Destination® Peripheral Guiding Sheath is designed to be used for the introduction of interventional and diagnostic devices into the human vasculature, including but not limited to lower extremity access via a contralateral approach.

The Destination® Renal Guiding Sheath is intended for the introduction of interventional and diagnostic devices into the human vasculature including but not limited to the renal arteries.

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

The Destination® 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 5.1: Summary of Substantial Equivalence

Device Characteristic	**New Device:** Destination® Guiding Sheath (Carotid, Peripheral and Renal)	**Primary Predicate:** Destination® Carotid Guiding Sheath	**Predicate:** Destination® Peripheral Guiding Sheath	**Predicate:** Destination® Renal Guiding Sheath
510(k)	None	K052185	K091329	K081045
Manufacturer	Terumo Medical Corporation	Same	Same	Same
Intended Use / Indications for Use	Carotid: Same Peripheral: Same Renal: Same	The Destination® Carotid 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 Destination® Peripheral Guiding Sheath is designed to be used for the introduction of interventional and diagnostic devices into the human vasculature, including but not limited to lower extremity access via a contralateral approach.	The Destination® Renal Guiding Sheath is intended for the introduction of interventional and diagnostic devices into the human vasculature including but not limited to the renal arteries.
Operation Principle	Operated manually or by a manual process;	Same	Same	Same
Design / Construction	Sheath, Dilator, Hemostatic Valve with side tube and three-way stopcock, and Dilator Retaining Clip	Same	Same	Same

Device Characteristic	**New Device:** Destination® Guiding Sheath (Carotid, Peripheral and Renal)	**Primary Predicate:** Destination® Carotid Guiding Sheath	**Predicate:** Destination® Peripheral Guiding Sheath	**Predicate:** Destination® Renal Guiding Sheath
Materials	**Sheath Assembly** Same except for the materials grade changes	**Sheath Assembly** **Tubing:** PTFE – SSL coil – Nylon **Tip:** Nylon **Hydrophilic Coating:** Polyvinylpyrrolidone-based coating **Hub:** Nylon **Radiopaque Band:**Gold	**Sheath Assembly** Same	**Sheath Assembly** Same
	Dilator Assembly Same	**Dilator Assembly** **Tubing:** Polypropylene/ Thermoplastic Elastomer Blend **Hub:** Polypropylene **Coating:** Reactive Silicone **Caulking Pin:** Stainless steel	**Dilator Assembly** Same	**Dilator Assembly** Same
	Tuopy-Borst Valve (TBV): Same	**Tuopy-Borst Valve (TBV):** **Y-Connector Assembly:** Polycarbonate, Silicone **Side Tube/3-Way Stopcock Assembly:** Polybutadiene, Polycarbonate, High Density Polyethylene Base Resin and HDPE colorants, Polypropylene	**Tuopy-Borst Valve (TBV):** Same	**Tuopy-Borst Valve (TBV):** Same

Device Characteristic	**New Device:** Destination® Guiding Sheath (Carotid, Peripheral and Renal)	**Primary Predicate:** Destination® Carotid Guiding Sheath	**Predicate:** Destination® Peripheral Guiding Sheath	**Predicate:** Destination® Renal Guiding Sheath
	Cross Cut Valve (CCV): Same	**Cross Cut Valve (CCV):** **Valve Assembly:** Polypropylene, Polycarbonate, Silicone Rubber Elastomer, Non-reactive silicone oil 1000cst **Side Tube/3-Way Stopcock Assembly:** Same as TBV	**Cross Cut Valve (CCV):** Same	**Cross Cut Valve (CCV):** Same
	Dilator Retaining Clip Same	**Dilator Retaining Clip** LDPE	**Dilator Retaining Clip** Same	**Dilator Retaining Clip** Same
Package	Unit Pouch Shelf Box Shipping Carton	Same	Same	Same

Device Characteristic	**New Device:** Destination® Guiding Sheath (Carotid, Peripheral and Renal)	**Primary Predicate:** Destination® Carotid Guiding Sheath	**Predicate:** Destination® Peripheral Guiding Sheath	**Predicate:** Destination® Renal Guiding Sheath
Specifications	Carotid: Same Peripheral: Same Renal: Same	Sheath Size: 6-7Fr. Nominal ID/OD: 6Fr.: 0.087”/0.111” 7Fr.: 0.101”/0.122” Sheath Length: 80-110 cm Hydrophilic Coating: Distal 15 cm Distal Shapes: ST, MP Dilator ID/OD (nominal): 6Fr.: 0.045”/0.084” 7Fr.: 0.045”/0.097” Dilator Extended Length: 5cm	Sheath Size: 5-8 Fr. Nominal ID/OD: 5Fr.: 0.076”/0.098” 6Fr.: (45cm): 0.087”/0.109” 6Fr.: (65cm, 90cm): 0.087”/0.111” 7Fr.: 0.101”/0.122” 8Fr.: 0.115”/0.136” Sheath Length: 45-110 cm Hydrophilic Coating: Distal 15-60 cm Distal Shapes: ST Dilator ID/OD (nominal): 5Fr.: 0.045”/0.072” 6Fr.: 0.045”/0.084” 7Fr.: 0.045”/0.097” 8Fr.: 0.045”/0.111” Dilator Extended Length: 2.5 cm for sheaths lengths up to 75cm, 5 cm for sheaths longer than 75cm	Sheath Size: 5-7 Fr. Nominal ID/OD: 5Fr.: 0.076”/0.098” 6Fr.: 0.087”/0.109” 7Fr.: 0.101” /0.122” Sheath Length: 45-55 cm Hydrophilic Coating: Distal 5 cm Distal Shapes: ST, HS, MP, RDC, LIMA Dilator ID/OD (nominal): 5Fr.: 0.045”/0.072” 6Fr.: 0.045”/0.084” 7Fr.: 0.045”/0.097” Dilator Extended Length: 2 cm

Device Characteristic	**New Device:** Destination® Guiding Sheath (Carotid, Peripheral and Renal)	**Primary Predicate:** Destination® Carotid Guiding Sheath	**Predicate:** Destination® Peripheral Guiding Sheath	**Predicate:** Destination® Renal Guiding Sheath
Sterilization	Ethylene Oxide (validated in accordance with ANSI / AAMI / ISO 11135-1 to achieve SAL 10^{-6})	Same	Same	Same
Shelf life	6 months	30 months	30 months	30 months
Disposable Single Use	Yes	Same	Same	Same

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

Performance

Performance testing was conducted to ensure that the Destination® 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 Destination® Guiding Sheath.

Table 5.2: Summary of Performance Testing

Test Item	Reference	Component
Lubricity and Durability/Adhesion	In-house standard	Sheath
Simulated Use and Particulate	FDA Guidance Doc 1608	Sheath, Dilator, CCV
Simulated Use Coating Integrity Evaluation	FDA Guidance Doc 1608	Sheath

The Destination® 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 Destination® Guiding Sheath is substantially equivalent for its intended use.

Biocompatibility

The Destination Guiding Sheaths were evaluated for biological safety based on its body contact and duration per FDA Guidance on Use of International Standard ISO 10993-1 and EN ISO 10993-1.

The Destination 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 for 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

*Complement activation tests are not a requirement for ISO 10993-4 for external communicating devices, circulating blood with limited exposure (<24 hours). This testing was completed since FDA has previously requested this testing for similar devices. ISO 10993-4/Amd 1: 2006 indicated complement activation testing should be evaluated for devices with prolonged exposure (>24 hours).

Results of the testing demonstrate biocompatibility of the finished Destination® 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}.

Destination® 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 Destination® 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):

- Predicate Device: K052185 – Destination® Carotid Guiding Sheath, manufactured by Terumo Medical Corporation
- Predicate Device: K091329 – Destination® Peripheral Guiding Sheath, manufactured by Terumo Medical Corporation
- Predicate Device: K081045 – Destination® Renal Guiding Sheath, manufactured by Terumo Medical Corporation