August 1, 2019

Freudenberg Medical LLC
Mary Prunty
Regulatory Affairs Manager
2301 Centennial Boulevard
Jeffersonville, Indiana 47130

Re: K191190
Trade/Device Name: Steerable Introducer 8.5F
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: May 1, 2019
Received: May 3, 2019

Dear Mary Prunty:

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,

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191190

Device Name

Indications for Use *(Describe)*

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."

510(K) SUMMARY

GENERAL INFORMATION

Primary Submission Contact

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Date of Summary

01 May 2019

DEVICE INFORMATION

Device Information	
Trade Name	Steerable Introducer
Common Name	8.5F Steerable Introducer S/M/L
Classification Name	Catheter Introducer
Classification Regulation	870.1340
Class	II
Panel	Cardiovascular
Product Code	DYB
Predicate Device(s)	Agilis NxT™ Steerable Introducer Large Curl (K081645) Agilis NxT™ Steerable Introducer Small/Medium Curl (K061363)

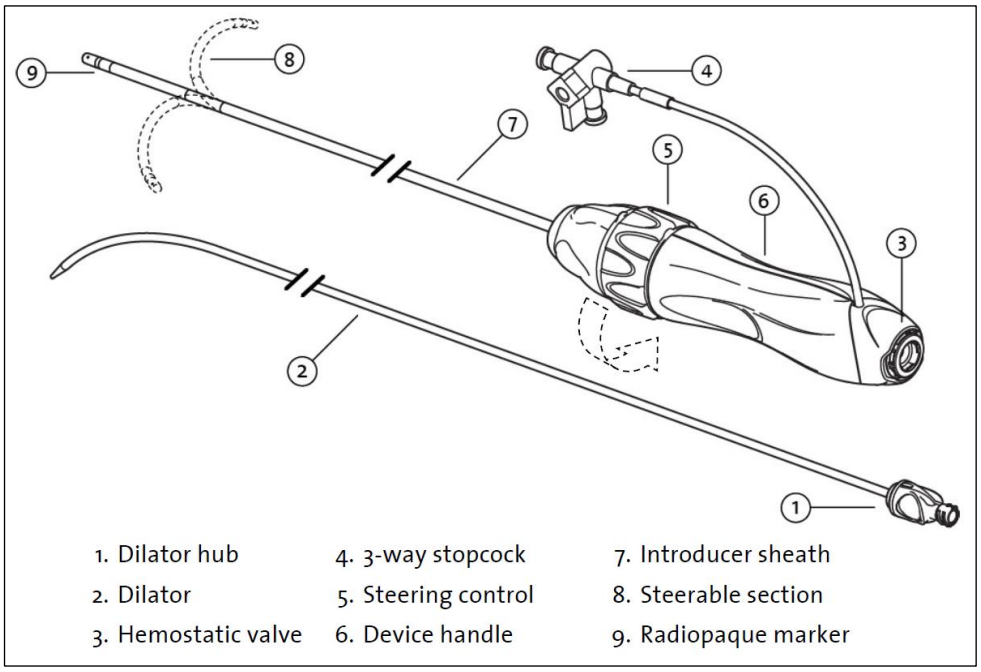
510(K) TYPE AND REASON FOR SUBMISSION

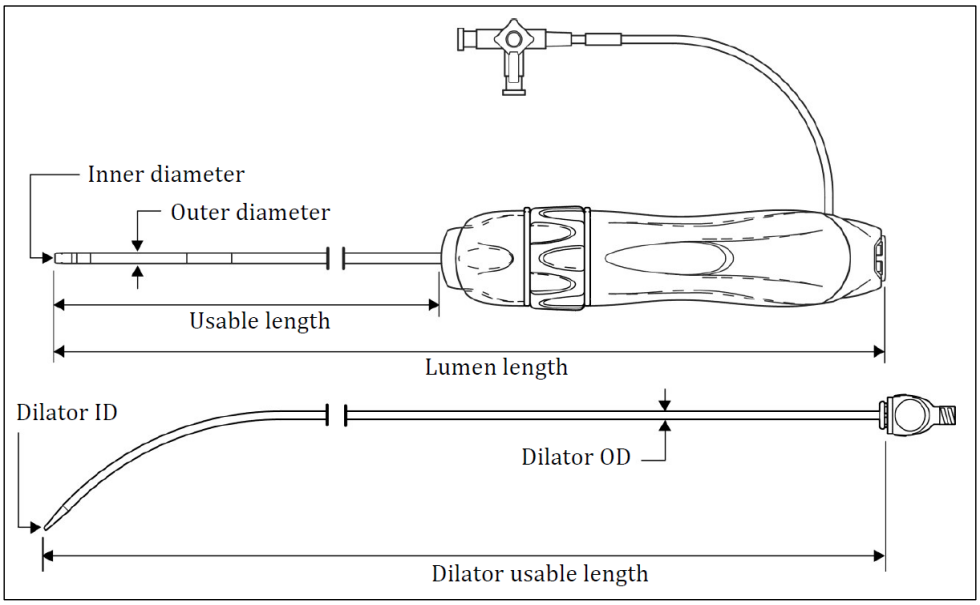
This is a traditional 510(k) and is submitted to obtain marketing clearance for a new device – the 8.5F Steerable Introducer, with small, medium and large curl.

DEVICE DESCRIPTION

The steerable introducer consists of a steerable sheath connected to a handle with steering controls, a hemostasis valve with sideport featuring a 3-way stopcock, and a tapered dilator. The device is provided sterile in a sealed Tyvek pouch and carton with IFU. The sheath distal tip and dilator shaft are radiopaque for visualization under fluoroscopy. The dilator is designed to accommodate a guidewire, with size compatibility as indicated on the product labels. A dilator hub is provided with a female luer tapered fitting for flushing (see illustration below). The device includes a side port with stopcock to allow fluid injection and sampling, drip infusion, pressure monitoring, flushing and aspiration.

The steerable introducer usable length, lumen length, outer diameter, curl size, and inner diameter/tool compatibility specifications are indicated on the product labels. The distal end of the steerable sheath features 180° bi-directional deflection to provide directional control to the compatible tools interacting with the device.





INTENDED USE

The 8.5F Steerable Introducer is intended to provide a conduit allowing introduction, removal, and exchange of compatible therapeutic and/or diagnostic tools into the cardiovascular system while maintaining hemostasis. The device facilitates access to the left and right sides of the heart, including left atrium and left ventricle access through the interatrial septum. It features a deflectable distal tip that enables guidance of compatible tools.

INDICATIONS FOR USE

The Steerable Introducer is indicated when introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

TECHNOLOGICAL CHARACTERISTICS

The 8.5F Steerable Introducer (Small / Medium / Large Curl) are comparable to the predicate devices previously cleared under K061363 (Small / Medium Curl) & K081645 (Large Curl), with the following similarities:

- Indications for Use
- Fundamental scientific technology
- Basic sheath design (dimensions, tip shape)
- User interface with handle (rotating actuator for deflection)
- Materials
- Sterilization process

The 8.5F Steerable Introducer distal tip is radiopaque for visualization under fluoroscopy to facilitate introduction into the cardiovascular system and features 180° bi-directional deflection to provide directional control to the compatible tools interacting with the device. A steering control knob is provided on the handle, along with a hemostasis valve and flush port with 3-way stop-cock to allow fluid injection and sampling, drip infusion, pressure monitoring, flushing and aspiration. The included dilator is radiopaque for visualization under fluoroscopy. It is sized for a close fit to the introducer sheath and accommodates insertion over the included 0.032in guidewire and standard 98cm transseptal needle. A proximal dilator hub includes a female luer tapered fitting for flushing.

PERFORMANCE DATA

The 8.5F Steerable Introducer has been tested to meet the device intended use and to ensure conformance to the product specifications. The 8.5F Steerable Introducer has been tested and meets all its physical and performance specifications on the bench including, but not limited to:

- Shaft deflection
- Simulated Use
- Torsional stiffness
- Radiopacity visualization
- Hemostasis

- Leak testing
- Guidewire compatibility
- Transseptal needle compatibility
- Distribution tests
- Usability studies

SHELF LIFE TESTING

Shelf life verification testing was completed with a 13 month accelerated age study to ensure that device specifications were met. All testing passed. Testing demonstrated the functional and mechanical characteristics of the device were not compromised post aging.

BIOCOMPATIBILITY

In addition, the 8.5F Steerable Introducer was tested for biocompatibility as per ISO 10993-1 for limited exposure (<24 hours) to circulating blood. The device is to be sterilized by ethylene oxide to a sterility assurance level (SAL) of $10^{-6.}$ These performance requirements are similar to those described by the predicate device. The testing demonstrated the device satisfies ISO 10993-1 requirements, indicating the device is as safe and effective as the predicate device.

SUBSTANTIAL EQUIVALENCE

The 8.5F Steerable Introducer is substantially equivalent to the Agilis NxT™ Steerable Introducer Large Curl (K081645 Model G408324) and Agilis NxT™ Steerable Introducer Small/Medium Curl (K061363). The 8.5F Steerable Introducer has the same intended use for introducing compatible therapeutic / diagnostic tools into the chambers of the heart. Test data demonstrate the technological difference between the Steerable Introducer and its predicate do not raise any safety and efficacy issues.

CONCLUSION

Based on the test data and the same intended use, the 8.5F Steerable Introducer is found to be substantially equivalent to its predicate.