



December 11, 2023

Boston Scientific Corporation
Nicholas Zurn
Regulatory Affairs Specialist II
4100 Hamline Avenue North
St. Paul, Minnesota 55112

Re: K233248

Trade/Device Name: FARADRIVE™ Steerable Sheath
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: September 28, 2023
Received: September 28, 2023

Dear Nicholas Zurn:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K233248

Device Name

FARADRIVE™ Steerable Sheath

Indications for Use (Describe)

The FARADRIVE Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum.

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 in Compliance with 21 CFR 807.92

Submitter Information:

Submitter Name: Boston Scientific Corporation

Submitter Address: 4100 Hamline Avenue North
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Date Prepared: 28-September-2023

Device Information:

Generic Name: Steerable Sheath

Trade Name: FARADRIVE™ Steerable Sheath

Product Code: DRA (Catheter, Steerable)

510(k) Number: K233248

Device Class: Class II

Review Panel: Cardiovascular (DRA)

Classification Regulations: 21 CFR 870.1280

Predicate Device Information:

POLARSHEATH™ Steerable Sheath 12F

Manufacturer: Boston Scientific Corporation

510(k) #: K223824

FDA Clearance Date: March 22nd, 2023

Product Code: DRA

Reference Device Information:

MitraClip G4 Steerable Guide Catheter

Manufacturer: Abbott Medical

510(k) #: K190167

FDA Clearance Date: May 29th, 2019

Product Code: DRA

Indications for Use:

The FARADRIVE Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum.

Device Description:

The FARADRIVE Steerable Sheath is used to facilitate access to the vasculature and into the chambers of the heart. The handle is furnished with a rotating Actuator Knob that enables a single plane unidirectional deflection and has the ability to actively straighten the distal end of the FARADRIVE Steerable Sheath curve when rotated.

The FARADRIVE Steerable Sheath includes an integral hemostasis valve to minimize blood loss or air ingress during catheter and dilator manipulation and a side flush line with three-way stopcock for blood aspiration, fluid infusion, blood sampling and pressure monitoring. The sheath also includes distal vent holes to facilitate aspiration and minimize cavitation. The supplied dilator is shaped to assist in facilitating vascular or chamber access when fully inserted into the sheath. The proximal end of the dilator includes a feature that will lock to the sheath hub when fully inserted.

Substantial Equivalence & Comparison of Technological Characteristics:

Table 1 - COMPARISON OF THE SUBJECT FARADRIVE STEERABLE SHEATH VERSUS PREDICATE POLARSHEATH STEERABLE SHEATH 12F

Characteristic	Predicate Device (K223824) POLARSHEATH Steerable Sheath 12F (Boston Scientific Corporation)	Subject Device (K233248) FARADRIVE Steerable Sheath (Boston Scientific Corporation)
Indication for Use	The POLARSHEATH™ steerable sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart.	The FARADRIVE Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart, including the left side of the heart through the interatrial septum.
Single Use or Reusable	Single Use	Single Use
Shaft Design	Deflectable shaft with single lumen	Deflectable shaft with single lumen
Deflection	Unidirectional to 155°	Unidirectional to 180° with active straightening back to 0°
Hemostasis Valve	Yes	Yes
Side Flush Port Tubing	Yes	Yes
Stopcock	No	Yes
Braided Shaft	Yes	Yes
Radiopaque Marker(s)	Yes	Yes
Guidewire Compatibility	0.032 inches (0.81mm) and 0.035 inches (0.89mm)	0.035 inches (0.89mm)
Sterilization	Provided sterile via Ethylene Oxide	Provided sterile via Ethylene Oxide
Packaging	Tyvek nylon/polyethylene pouch	Tyvek nylon/polyethylene pouch
Shelf Life	12 months	24 months
Sheath Dimensions		
Overall Length	82cm	91cm
Usable Length	68cm	74cm
Sheath OD	5.3mm (15.9Fr)	5.8mm (17.4Fr)

Characteristic	Predicate Device (K223824) POLARSHEATH Steerable Sheath 12F (Boston Scientific Corporation)	Subject Device (K233248) FARADRIVE Steerable Sheath (Boston Scientific Corporation)
Sheath ID	4.2mm (12.7Fr)	4.3mm (13Fr)
Dilator Dimensions		
Dilator Usable Length	85cm	94cm
OD	0.159 inches	0.163 inches
ID	0.039 inches	0.037 inches
Materials		
	- Pebax with stainless steel braid and PTFE liner - Silicone Rubber - Polycarbonate - Polyethylene	- Pebax, Nylon 12, with stainless steel braid and hydrophilic coated Pebax liner - Silicone Rubber - Polycarbonate - Polyethylene

Summary of Non-Clinical Performance Testing:

The non-clinical performance testing included in this 510(k) application provides evidence that the FARADRIVE Steerable Sheath conforms to user needs and its intended use and is thus substantially equivalent to the predicate previously cleared under K223824. No new safety or effectiveness issues were raised during device performance testing. The following test data is provided in this 510(k) application:

- Sterilization validation, including EO Cycle Validation and Product Qualification, for the sterile FARADRIVE Steerable Sheath
- Biocompatibility assessment and testing for the patient-contacting components of the FARADRIVE Steerable Sheath
- Design verification testing of the FARADRIVE Steerable Sheath and its packaging, demonstrating that the device and its packaging meets the design input requirements as per the product and packaging specifications
 - Design verification testing at nominal (T=0) timepoint
 - Design verification testing at an accelerated aging timepoint for a labeled shelf life of T=24 months
- Design validation testing summary for the FARAPULSE Pulsed Field Ablation System demonstrating that the system conforms to user needs and intended use

Conclusion:

Based on the intended use, fundamental technological characteristics, and performance testing, the proposed FARADRIVE Steerable Sheath device has shown to be appropriate for its intended use and is substantially equivalent to the predicate device.