July 24, 2026

Boston Scientific Corporation
Mariafernanda Marroquin
Regulatory Affairs Specialist
4100 Hamline Ave. N.
Saint Paul, Minnesota 55112

Re: K262165
Trade/Device Name: FARADRIVE™ Steerable Sheath (M004PF21M402)
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA
Dated: June 26, 2026
Received: June 26, 2026

Dear Mariafernanda Marroquin:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

for HETAL B. ODOBASIC -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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262165

Please provide the device trade name(s).

FARADRIVE™ Steerable Sheath

Please provide your Indications for Use below.

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.

Please select the types of uses.

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
- ☐ Infants (29 days old to < 2 years old)
- ☐ Children (2 years old to < 12 years old)
- ☐ Adolescents (12 years old to < 22 years old)
- ☐ Adults (22 years old and greater)

510(k) Summary in Compliance with 21 CFR 807.92

Submitter Information:

Submitter Name: Boston Scientific Corporation

Submitter Address: 4100 Hamline Avenue North
St. Paul, Minnesota
55112-5798 USA

Contact: Mariafernanda Marroquin Gonzalez
Regulatory Affairs Specialist III
Phone: +506 8488-2687
Email: Mariafernanda.MarroquinGonzalez@bsci.com

Date Prepared: 26-June-2026

Device Information:

Generic Name: Steerable Sheath

Trade Name: FARADRIVE™ Steerable Sheath

Product Code: DRA (Catheter, Steerable).

Device Class: Class II

Review Panel: Cardiovascular (DRA)

Classification Regulations: 21 CFR 870.1280

Predicate Device Information:

FARADRIVE™ Steerable Sheath

Manufacturer: Boston Scientific Corporation
510(k) #: K233248
FDA Clearance Date: December 11th, 2023,
Product Code: DRA

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.

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.

Substantial Equivalence & Comparison of Technological Characteristics:

The FARADRIVE Steerable Sheath subject device maintains the same intended use and indications for use as the predicate device (K233248). The subject and predicate devices are identical with respect to design, materials, fundamental scientific technology, principles of operation, environment of use, packaging configuration, and sterilization method. The only changes between the predicate and subject devices are limited to labeling updates to the Instructions for Use (IFU), including enhanced guidance on dilator insertion technique and the addition of a warning. These modifications do not alter the device's technological

characteristics and do not raise new or different questions of safety or effectiveness. Verification and validation activities, including risk assessment and usability evaluation, support that the modified device remains substantially equivalent to the predicate device.

Table 1 - COMPARISON OF THE SUBJECT FARADRIVE STEERABLE SHEATH VERSUS PREDICATE COMMERCIALLY AVAILABLE FARADRIVE STEERABLE SHEATH

Characteristic	Subject Device FARADRIVE™ Steerable Sheath (Boston Scientific Corporation)	Comment
Intended Use/ Indications for Use	Identical	Both subject and predicate device are indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart.
Operating principles	Identical	The operating principle for both subject and predicate device is to provide percutaneous introduction into the vasculature.
Environment of use	Identical	Both the predicate and subject devices are intended for use within electrophysiology labs.
Materials	Identical	Both the predicate and subject device contain the same materials.
Technological characteristics (dimensions, design)	Identical	Both the predicate and subject device share identical Technological characteristics.
Labelling	Similar	The subject device labelling has modifications to reflect the associated changes: • Clarifying Instructions For

Characteristic	Subject Device FARADRIVE™ Steerable Sheath (Boston Scientific Corporation)	Comment
		Use to ensure proper dilator insertion technique.
Packaging configuration	Identical	The predicate and subject device contain the same packaging configuration (tray, pouch, shelf carton and shipper box)
Sterilization Method	Identical	Both subject and predicate device are Single Use, Ethylene Oxide sterilized

Summary of Non-Clinical Performance Testing:

All previously completed non-clinical verification and validation testing—including bench performance, biocompatibility, sterilization, shelf life, and animal (design validation) studies—remain applicable, as the subject device maintains the same fundamental design, materials, and intended use as the predicate device.
A Human Factors summative (validation) study was conducted with representative users to evaluate impacted critical tasks under simulated-use conditions. Results demonstrate that users can perform these tasks safely and effectively and confirm that the FARADRIVE™ Steerable Sheath continues to meet user needs and intended use. No new safety or effectiveness concerns were identified, supporting substantial equivalence to the predicate device (K233248).

Conclusion:

The subject and predicate devices share the same indications for use, intended use, and principles of operation. Labelling differences between the subject and predicate devices do not raise new or different questions of safety and effectiveness. The results of verification and validation activities support substantial equivalence of the proposed FARADRIVE™ Steerable Sheath to the predicate device.