May 15, 2026

Boston Scientific Coporation
Ms. Rosemary Bush
Regulatory Affairs Specialist
300 Boston Scientific Way,
Marborough, MA 01752 USA

Re: K260771
Trade/Device Name: TruSelect 2.6 Microcatheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: April 15, 2026
Received: March 9, 2026

Dear Ms. Rosemary Bush:

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,

JENNY R. KATSNELSON -S

Digitally signed by JENNY R. KATSNELSON -S
Date: 2026.05.15 17:59:26 -04'00'

for Lydia Glaw
Assistant Director
DHT2C: Division of Coronary and
Peripheral Intervention 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260771

Device Name
TruSelect 2.6 Microcatheter

Indications for Use *(Describe)*
The TruSelect 2.6 Microcatheter is intended to provide a conduit for the selective infusion of diagnostic, embolic, or therapeutic agents to target vessels within the peripheral vasculature during endovascular procedures. The microcatheter is coaxially tracked over a steerable guidewire to access the distal peripheral vasculature. Diagnostic, embolic, or therapeutic agents should be used in accordance with specifications outlined by the manufacturer.

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

A 510(k) summary complying with the requirements of 21 CFR 807.92.

I. SUBMITTER INFORMATION

Submitter Name: Boston Scientific Corporation

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Associate Director Regulatory Affairs, Boston Scientific Corporation
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Date Prepared: March 9, 2026

II. DEVICE INFORMATION

Device trade name: TruSelect™ 2.6 Microcatheter.

Tables 1 and 2 below summarize the relevant subject device information.

Table 1: TruSelect™ 2.6 Microcatheter Universal Part Number (UPN)

Material Reference Universal Product Number (UPN)	Catheter Length (cm)	Tip Shape	Radiopaque Marker
M00139735105010	105	Straight	1
M00139735130010	130	Straight	1
M00139735155010	155	Straight	1
M00139735155020	155	Straight	2
M00139735105110	105	Bern	1
M00139735130110	130	Bern	1
M00139735155110	155	Bern	1
M00139735155120	155	Bern	2

Table 2: Additional Device Information

Common or Usual name	Regulation Classification Number	Regulation Classification Name	Product Code	Product Code Name	Regulatory Class
Microcatheter	21 CFR 870.1210	Continuous Flush Catheter	KRA	Continuous Flush Catheter	Class II

III. PREDICATE DEVICE IDENTIFICATION

Predicate Device
TruSelect™ Microcatheter (K201792, cleared on July 28, 2020), Boston Scientific Corporation

IV. DEVICE DESCRIPTION

The TruSelect 2.6 Microcatheter is a low profile 2.6F microcatheter intended to provide a conduit for the selective infusion of diagnostic, embolic, or therapeutic agents to target vessels within the peripheral vasculature during endovascular procedures. The microcatheter is coaxially tracked over a steerable guidewire to access the distal peripheral vasculature. The microcatheter is torqueable to aid in anatomical selection. When access is established, the microcatheter is utilized for delivery of diagnostic, embolic or therapeutic agents.

The TruSelect 2.6 Microcatheter has a distal outside diameter (OD) of 2.6F (0.88 mm), and a maximum OD of 2.9F (0.98 mm). It is compatible with a guide catheter with minimum internal diameter (ID) 0.040 inch (1.02 mm). The microcatheter has a straight lumen ID 0.025 inch (0.64 mm). The microcatheter lumen accommodates steerable guidewires with maximum OD of 0.021 inch (0.53 mm). The device is compatible with irregular particles up to 710 microns, spherical embolics up to 900 microns and embolic coils size 0.018" (0.46 mm) suitable for delivery through 0.025 inch ID microcatheters.

TruSelect 2.6 Microcatheter is available in a range of lengths (105, 130, 155 cm) and two tip shapes (straight or bern) to aid in accessing challenging anatomy. The proximal end incorporates a standard luer compatible with ancillary devices such as rotating hemostatic valve (RHV) or Y-Adapter. The braided catheter shaft design enables advancement and directional control from the proximal end. The flexible distal end enables smooth tracking of the device through tortuous anatomy. The distal section of the microcatheter is shapeable. The distal outer surface has a hydrophilic coating to reduce friction during use. Each microcatheter features a single radiopaque (RO) marker at the distal tip to facilitate fluoroscopic visualization. Two of the 155 cm length TruSelect 2.6 Microcatheters also include a second RO marker, positioned 3 cm proximally to the tip.

Devices are packaged in a carrier tube hoop and placed within a sterile barrier pouch. Accessories include a Y-Adaptor and microcatheter introducer within a separate accessory pouch.

The TruSelect 2.6 Microcatheters are provided sterile, using 100% ethylene oxide (EO) gas sterilization, and are intended for single use only by physicians experienced in percutaneous, peripheral intravascular and diagnostic techniques and procedures within environmental conditions typical for hospital catheterization settings.

V. INDICATIONS FOR USE

Intended use is the same for the subject and predicate devices.

TruSelect 2.6 Microcatheter (Subject Device)	**TruSelect Microcatheter (Predicate Device)**
The TruSelect 2.6 Microcatheter is intended to provide a conduit for the selective infusion of diagnostic, embolic, or therapeutic agents to target vessels within the peripheral vasculature during endovascular procedures. The microcatheter is coaxially tracked over a steerable guidewire to access the distal peripheral vasculature. Diagnostic, embolic, or therapeutic agents should be used in accordance with specifications outlined by the manufacturer.	The TruSelect 2.6 Microcatheters are intended for peripheral vascular use. The microcatheter can be used for selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

TruSelect 2.6 Microcatheter, and predicate, TruSelect Microcatheter (K201792, cleared on July 28, 2020) are similar in fundamental design technology, operating principle, function and sterilization method. There are differences in materials, dimensions and packaging for the subject device, as documented in the following table, in comparison to the predicate device.

Materials	Catheter shaft materials and hydrophilic coating differ from predicate.
Dimensions	The subject device single lumen catheter shaft lengths and tip ID, OD and lengths are within the range of predicate device dimensions. Luer lock dimensions are the same.
Packaging	The subject and predicate devices are packaged within a carrier tube placed within a sterile pouch and shelf carton. The predicate device includes printed Instructions For Use (IFU); the subject device comes with an electronic IFU insert notification.

Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. The results of bench testing helps establish substantial equivalence between the subject and predicate devices.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

Biocompatibility and non-clinical laboratory bench testing were performed to support the determination of substantial equivalence between the TruSelect 2.6 Microcatheter and the predicate TruSelect Microcatheter. Testing was performed using well-established test methods. The TruSelect 2.6 Microcatheters were also subjected to testing as per Guidance for Industry and FDA Staff, Peripheral Percutaneous Transluminal Angioplasty (PTA) and Specialty Catheters - Premarket Notification (510(k)) Submissions, issued on 14 April 2023.

The following biocompatibility tests were completed on TruSelect 2.6 Microcatheter.

- Hemocompatibility ISO 10993-4
- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Irritation / Intracutaneous reactivity ISO 10993-10; 10993-23
- Material Mediated Pyrogenicity ISO 10993-11
- Acute Systemic Toxicity ISO 10993-11

The following non-clinical performance tests were performed on TruSelect 2.6 Microcatheter.

- Manifold Connection
- Guidewire Exchange Compatibility
- Guide Catheter Compatibility
- Y-adapter Compatibility
- Catheter proximal, distal and tip OD
- Catheter lumen ID
- Tip Shape Angle (Bern)
- Tip Shapeability
- Marker Band Location(s) / Tip Length
- Effective Length
- Microcatheter Coating Length
- Microcatheter Coating Lubricity & Durability

- Device trackability
- Distal End Flexibility (Distal 5cm)
- Proximal End Stiffness
- Proximal Shaft Kink
- Distal Shaft Kink
- Full Catheter Tensile
- Tip & Marker Band Tensile
- Torque Strength
- Radiopacity
- Infusion Stability
- Flow Rate
- Dead Space Volume
- Max Infusion Pressure
- Static Burst
- Chemical Compatibility
- Microcatheter to Microspheres Compatibility
- Microcatheter to PVA particle Compatibility
- Microcatheter to .018 Embolic Coil Compatibility
- Simulated Use Particulate Matter
- Corrosion Resistance
- Packaging
- Shelf life

The results of these tests verify the subject device performance characteristics and assure conformance to the requirements for its intended use.

VIII. CONCLUSION

The subject device, Truselect 2.6 Microcatheter, is substantially equivalent to the predicate device, TruSelect Microcatheter (K201792, cleared on July 28, 2020). The subject and predicate devices share the same intended use and fundamental scientific technology, including principle of operation. Differences in technological characteristics between the subject and predicate devices do not raise different questions of safety and effectiveness. Non-clinical performance evaluations support substantial equivalence of TruSelect 2.6 Microcatheter to the predicate device.