April 8, 2026

Boston Scientific
Brian Li
Sr. Regulatory Affairs Specialist
1 Boston Scientific Way
Maple Grove, Minnesota 55369

Re: K260816

Trade/Device Name: OptiCross™ Coronary Imaging Catheter (H749518110);
OptiCross™ 6 Coronary Imaging Catheter (H7495181160);
OptiCross™ HD Coronary Imaging Catheter (H74939352040);
OptiCross™ 6 HD Coronary Imaging Catheter (H74939354080);
OptiCross™ Coronary Imaging Catheter (Bagless) (H749518130);
OptiCross™ 6 Coronary Imaging Catheter (Bagless) (H7495181360);
OptiCross™ HD Coronary Imaging Catheter (Bagless) (H74939352050);
OptiCross™ 6 HD Coronary Imaging Catheter (Bagless) (H74939354090)

Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: March 12, 2026
Received: March 13, 2026

Dear Brian Li:

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: MARCO CANNELLA -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.	K260816

Please provide the device trade name(s).

OptiCross Coronary Imaging Catheter (H749518110);
OptiCross 6 Coronary Imaging Catheter (H7495181160);
OptiCross HD Coronary Imaging Catheter (H74939352040);
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OptiCross HD Coronary Imaging Catheter (Bagless) (H74939352050);
OptiCross 6 HD Coronary Imaging Catheter (Bagless) (H74939354090)

Please provide your Indications for Use below.

This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Please select the types of uses (select one or both, as applicable).

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

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510(k) Summary
per 21 CFR 807.92

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA
Contact Name and Information	Brian Li Sr. Regulatory Affairs Specialist Phone: (763) 258-7789 E-mail: Brian.Li@bsci.com
Date Prepared	12-March-2026
Proprietary Name	OptiCross™ Coronary Imaging Catheter OptiCross™ 6 Coronary Imaging Catheter OptiCross™ HD Coronary Imaging Catheter OptiCross™ 6 HD Coronary Imaging Catheter OptiCross™ Coronary Imaging Catheter (Bagless) OptiCross™ 6 Coronary Imaging Catheter (Bagless) OptiCross™ HD Coronary Imaging Catheter (Bagless) OptiCross™ 6 HD Coronary Imaging Catheter (Bagless)
Common Name	Diagnostic Intravascular Catheter Ultrasound Transducer
Classification Name	Primary: Catheter, Ultrasound, Intravascular (OBJ) has been classified as Class II per 21 CFR 870.1200 Subsequent: Transducer, Ultrasonic, Diagnostic (ITX) has been classified as Class II per 21 CFR 892.1570
Product Code	Primary: OBJ (Catheter, Ultrasound, Intravascular) Subsequent: ITX (Transducer, Ultrasonic, Diagnostic)
Classification	Class II, 21 CFR 870.1200 and 21 CFR 892.1570
Predicate Device	OptiCross™ HD Coronary Imaging Catheter OptiCross™ 6 HD Coronary Imaging Catheter K230453 cleared 18-May-2023

Device Description

The OptiCross and OptiCross 6 40 MHz Coronary Imaging Catheters are sterile, short rail imaging catheters. Available in 5F and 6F sizes.
The OptiCross HD and OptiCross 6 HD 60 MHz Coronary Imaging Catheters are sterile, short rail imaging catheters. Available in 5F and 6F sizes.
All catheters consist of two main assemblies:
1. Imaging Core
2. Catheter Body

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The imaging core is composed of a hi-torque, flexible, rotating drive cable with a radial looking 40 MHz or 60 MHz ultrasonic transducer at the distal tip. An electro-mechanical connector interface at the proximal end of the catheter makes the connection to the Motordrive Unit (MDU5 PLUS™) Instrument. The MDU5 PLUS-catheter interface consists of an integrated mechanical drive socket and electrical connection.

The catheter body is comprised of four sections:

1. Hub Sub-Assembly
2. Telescope Sub-Assembly
3. Proximal Shaft
4. Distal Shaft with the Distal Guidewire Lumen

The distal shaft with the distal guidewire lumen and proximal shaft sections comprise the "working length" of the catheter, and the telescoping sub-assembly section remains outside of the guiding catheter.

The catheter body has a distal shaft with the distal guidewire lumen with proximal exit at 1.6 cm from the distal end. A radiopaque (RO) marker is embedded in the catheter body at 0.5 cm from the distal tip. Two insertion markers are located on the proximal shaft (a single insertion marker at 90 cm and a single insertion marker at 100 cm from the distal tip) for the 5F catheters; three insertion markers are located on the proximal shaft (a single insertion marker at 90 cm and a double insertion marker at 100 cm from the distal tip) for the 6F catheters. These markers facilitate estimation of catheter position relative to the distal tip of the guide catheter. The proximal shaft is attached to the telescoping sub-assembly section via a strain relief connection. The telescoping sub-assembly allows the imaging core to be advanced and retracted for 15 cm of linear movement. The corresponding movement of the transducer occurs from the proximal end of the guidewire exit port to the proximal end of the distal shaft with the distal guidewire lumen. The telescope sub-assembly has proximal markers for lesion length assessment, consisting of a series of marks spaced 1 cm apart on the telescope body.

A flush port with a one-way check valve is used to flush the interior of the catheter body and maintain a flushed condition. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging. The one-way check valve helps retain saline in the catheter during use.

The Coronary Imaging Catheter, 17.78 cm (7 in) extension tube, 3 cm^3 (3 cc) and 10 cm^3 (10 cc) syringes, and 4-way stopcock are provided in a single use sterilized package.

Intended Use/indications for Use

This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

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Comparison of Technological Characteristics

The OptiCross™, OptiCross™ 6, OptiCross™ HD, and OptiCross™ 6 HD Coronary Imaging Catheters incorporate substantially equivalent design, materials, fundamental technology, interface with the IVUS imaging system, sterilization process, and intended use as those featured in the predicate; OptiCross™ HD and OptiCross™ 6 HD Coronary Imaging Catheters.

- Additional design control requirements (product specifications) were established to formally define the acceptable torque transmission limits and kink resistance performance consistent with the existing device design.

The OptiCross™ and OptiCross™ 6 Coronary Imaging Catheters utilize a 40 MHz transducer used for imaging. The OptiCross™ HD and OptiCross™ 6 HD catheters utilize a 60 MHz transducer used for higher definition imaging. All catheters interface with the same IVUS imaging system in the same way as the predicate.

Non-Clinical Performance Data

Determination of substantial equivalence is based on an assessment of non-clinical performance bench testing verification data.

Bench Testing

Bench testing verification was performed to evaluate physical integrity, functionality, and performance of the OptiCross™, OptiCross™ 6, OptiCross™ HD, and OptiCross™ 6 HD Coronary Imaging Catheter devices. Performance criteria includes catheter robustness and performance requirements.

Clinical Performance Data

Not applicable; determination of substantial equivalence is not based on clinical performance data. Substantial equivalence is based on an assessment of non-clinical performance data.

Conclusion

Based on a comparison of intended use/indications for use, technological characteristics, and fundamental design technology, including non-clinical performance bench testing verification data, the modified devices (OptiCross™, OptiCross™ 6, OptiCross™ HD, OptiCross™ 6 HD, OptiCross™ (Bagless), OptiCross™ 6 (Bagless), OptiCross™ HD (Bagless), OptiCross™ 6 HD (Bagless)) and predicate devices per K230453 (OptiCross™ HD, OptiCross™ 6 HD), support a determination of substantial equivalence and raise no new issues of safety and effectiveness.