September 23, 2022

Boston Scientific Corporation
Cassie Clark
Regulatory Affairs Specialist II
1 Scimed Place
Maple Grove, Minnesota 55311

Re: K222568
Trade/Device Name: OptiCross™ 18 Peripheral Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: August 23, 2022
Received: August 24, 2022

Dear Cassie Clark:

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,

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

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)*
K222568

Device Name
OptiCross 18™ Peripheral Imaging Catheter

Indications for Use *(Describe)*
OptiCross™ 18 is intended for intravascular ultrasound examination of peripheral vessels only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

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.

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K222568
510(k) Summary
per 21 CFR §807.92

Sponsor	Boston Scientific Corporation 300 Boston Scientific Way Marlborough, Massachusetts 01752 USA		
Contact Name and Information	Cassie Clark One Scimed Place Maple Grove, MN 55311-1566 Phone: 763-494-1425 e-mail: Cassie.Clark@bsci.com		
Prepared by	Cassie Clark August 23, 2022		
Proprietary Name	OptiCross™ 18 Peripheral Imaging Catheter		
Common Name	Diagnostic Intravascular Catheter, Ultrasound Transducer		
Product Code	OBJ, ITX		
Classification	Catheter, Ultrasound, Intravascular (OBJ) has been classified as Class II per 21 CFR 870.1200 Transducer Ultrasonic (ITX) has been classified as Class II per 21 CFR 892.1570		
Predicate Device	OptiCross™ 18 Peripheral Imaging Catheter	K160514	June 22, 2016
Reference Devices	OptiCross™ 35 Peripheral Imaging Catheter	K200733	April 17, 2020
	OptiCross™ 6 Coronary Imaging Catheter	K213593	January 14, 2022

Device Description

The OptiCross 18 30 MHz Peripheral Imaging Catheter is a sterile, short rail imaging catheter.

It consists of two main assemblies:

1. Imaging Core

2. Catheter Body

The imaging core is composed of a hi-torque, flexible, rotating drive cable with a radial looking 30 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 three sections:

1. Distal Imaging Window Lumen

2. Proximal Shaft Lumen

3. Telescoping Section

The distal imaging window lumen and proximal shaft lumen sections comprise the “working length” of the catheter, and the telescoping section remains outside of the guiding catheter.

The catheter body has a distal imaging window 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. In addition, two insertion depth markers are located on the proximal shaft lumen at 90 cm and 100 cm from the distal tip to aid in estimating catheter position relative to the distal guide catheter tip. The proximal shaft lumen is attached to the telescoping section via a strain relief connection.

The telescoping shaft (section) 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 imaging window lumen. The telescope section 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.

Indications for Use / Intended Use

OptiCross 18 is intended for intravascular ultrasound examination of peripheral vessels only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.

Comparison of Technological Characteristics

The OptiCross™ 18 Peripheral 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™ 18 Peripheral Imaging Catheter K160514.

Minor design modifications are being implemented to the telescope design and the imaging core design to enhance device robustness and ease of use of the telescope. These changes are intended to harmonize design features across BSC’s imaging catheter portfolio with the same enhancements previously submitted and reviewed as part of K213593.

Non-clinical Performance Data

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

Bench Testing

Bench testing was performed to evaluate physical integrity, functionality, and performance of the OptiCross™ 18 Peripheral Imaging Catheters. Performance criteria includes imaging robustness requirements, catheter robustness requirements, dimensional requirements, and interface with compatible devices.

Clinical Testing

Performance testing from clinical studies is not required to demonstrate substantial equivalence of the OptiCross™ 18 Peripheral Imaging Catheters.

Conclusion

Based on the indications for use, technological characteristics, and performance testing, the OptiCross™ 18 Peripheral Imaging Catheters have been shown to be appropriate for their intended use and are considered to be substantially equivalent to the predicate device; OptiCross™ 18 Peripheral Imaging Catheter K160514.