April 17, 2020

Boston Scientific Corporation
Jennifer Foley
Regulatory Affairs Specialist
3 Scimed Place
Maple Grove, Minnesota 55311

Re: K200733
Trade/Device Name: OptiCross 35 15 MHz Peripheral Imaging Catheter
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: Class II
Product Code: ITX, OBJ
Dated: March 19, 2020
Received: March 20, 2020

Dear Jennifer Foley:

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,

Mark Fellman
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200733

Device Name
OptiCross 35 15 MHz Peripheral Imaging Catheter

Indications for Use *(Describe)*
The OptiCross 35 15 MHz Peripheral Imaging Catheter is intended for ultrasound examination of peripheral vascular pathology 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Contact Name and Information	Jennifer L. Foley, DVM Three Scimed Place Maple Grove, MN 55311-1566 Phone: 763-955-8049 Fax: 763-494-2222 Email: Jennifer.Foley@bsci.com
Proprietary Name	OptiCross 35 15 MHz Peripheral Imaging Catheter
Common Name	Transducer, Ultrasonic, Diagnostic Catheter, Ultrasound Intravascular
Product Code	ITX, OBJ
Classification	21 CFR 892.1570 – Transducer, Ultrasonic, Diagnostic 21 CFR 870.1200 – Catheter, Ultrasound Intravascular
Predicate Device	Atlantis PV Imaging Catheter (K080272), cleared March 11, 2008
Reference Device	OptiCross 18 30 MHz Peripheral Imaging Catheter (K160514), cleared June 22, 2016
Device Description	OptiCross 35 15 MHz Peripheral Imaging Catheter (OptiCross 35) is designed for use with BSC's iLab™ Ultrasound Imaging System equipment and the motor drive unit, MDU5 PLUS™. When used together, the catheter, the motor drive unit, and iLab System equipment form a complete imaging system that allows for ultrasonic visualization of the peripheral vasculature. OptiCross 35 consists of two main components: the telescoping section and the dual lumen sheath. The telescoping section remains exterior to the patient's body during use and allows the imaging core to be advanced and retracted over 25cm of linear movement. The dual lumen sheath has one lumen which surrounds the imaging core attached proximally to the hub, and the other lumen is for guidewire use. The imaging core is composed of a high-torque, flexible, rotating drive cable with an outward-looking ultrasonic transducer at the distal tip. The proximal hub provides an electro-mechanical interface between the catheter and the motor drive unit. There are 25 radiopaque gold markers, approximately 1 cm apart, beginning at the distal end of the imaging core, which ends with a radiopaque housing that contains the transducer. Heparinized saline is flushed within the catheter prior to use to act as an acoustic medium. The PZT transducer and the drive cable rotate independently from the

	sheath to provide 360° image resolution. The transducer converts electrical impulses sent by the motor drive into transmittable acoustic energy. Reflected ultrasound signals are converted back to electrical impulses, returned to the motor drive unit, and are ultimately processed by the iLab equipment for live visualization of intravascular structures.
Indications for Use/ Intended Use	OptiCross 35 15 MHz Peripheral Imaging Catheter is intended for ultrasound examination of peripheral vascular pathology only. Intravascular ultrasound imaging is indicated for patients who are candidates for transluminal interventional procedures.
Device Technology Characteristics and Comparison to Predicate Device	OptiCross 35 15 MHz Peripheral Imaging Catheter incorporates the following changes from the predicate Atlantis PV Imaging Catheter (K080272): an updated hub that aligns with other marketed OptiCross catheters; modified telescope markers; additional radiopaque markers along the distal portion of the catheter; a longer, smoother taper to the distal catheter tip; addition of a strain relief to prevent kinking; addition of equivalent materials within the sheath and drive cable due to vendor obsolescence; and updated packaging appropriate for the newly designed device.

Characteristic	**Predicate** **Atlantis PV (K080272)**	**Proposed** **OptiCross 35 (OC35)**
Intended Use	The Atlantis PV 15 MHz Peripheral Imaging Catheter is intended for intravascular ultrasonic visualization.	The OptiCross 35 15 MHz Peripheral Imaging Catheter is intended for intravascular ultrasonic visualization.
Indications for Use	The Atlantis PV Peripheral Imaging Catheter is intended for ultrasound examination of peripheral pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.	The OptiCross 35 Peripheral Imaging Catheter is intended for ultrasound examination of peripheral vascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures.
Catheter Design	Sheath, Imaging Core with Telescope Section	Sheath, Imaging Core with Telescope Section
SAL	10^{-6}	10^{-6}
Packaging	Carrier tube assembly contained within a thermoformed tray and a poly-Tyvek pouch, stored in a shelf carton	Carrier tube assembly contained within a thermoformed tray and a poly-Tyvek pouch, stored in a shelf carton
Accessories	3cc and 10cc syringes, 4-way stopcock, extension set	3cc and 10cc syringes, 4-way stopcock, extension set
Single-Use	Yes	Yes
Specifications		
Guidewire Compatibility	0.035” (0.89mm)	0.035” (0.89mm)
Sheath Compatibility	≥ 8.5 F	≥ 8 F
Working Length	95 cm	105 cm
Sheath Design	Dual Lumen	Dual Lumen

Distal Markers	Radiopaque catheter tip	Radiopaque catheter tip plus 25 additional radiopaque markers, 1 cm apart
Dual Lumen Sheath OD (max)	0.111”	0.108”
Biocompatibility	Meets all the requirements in accordance with ISO 10993-1	Meets all the requirements in accordance with ISO 10993-1
Scanning Method	Rotary Driveshaft	Rotary Driveshaft
Mode of Operation	B-Mode, Autoscanning	B-Mode, Autoscanning
Image Rate	30 Hz Maximum	30 Hz Maximum
Sector Angle	360 Degrees	360 Degrees
Transducer Frequency	15 MHz	15 MHz
Acoustic Output	Below FDA Track 1 limits	Below FDA Track 1 limits

Non-Clinical Performance Data

Determination of substantial equivalence is based on an assessment of non-clinical performance bench testing, including bench-top performance evaluations, packaging validation, biological safety, electromagnetic compatibility, and acoustic output testing.

Bench Testing:
Bench testing was performed to evaluate physical integrity, functionality, and performance of the catheter. Performance criteria includes: deliverability, guidewire and sheath compatibility, image quality, non-uniform rotational distortion, measurement accuracy, general imaging capabilities, dimensional requirements, catheter tensile strengths, freedom from leak, visibility under fluoroscopy, interface with ancillary devices, environmental requirements, user interface requirements, corrosion resistance and particulates.

Biological Safety Testing:
Biocompatibility testing in accordance with ISO 10993-1, microbial assessments including bioburden and endotoxin, and pyrogenicity and sterility assurance testing show the device is biocompatible for its intended use.

Electrical and Mechanical Safety:
Acoustic Output was evaluated in accordance with FDA Guidance, *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* (June 27, 2019). Acoustic Output test results for the OptiCross 35 15 MHz Peripheral Imaging Catheter are below the FDA Track 1 limits. Electromagnetic compatibility testing was also conducted demonstrating compliance to IEC 60601-1-2 (4th Edition) and IEC 60601-2-37 (Edition 2.1).

Packaging Validation:
The integrity of the packaging configuration was evaluated in accordance with ISO 11607-1 and ISO 11607-2. Testing was conducted on fully packaged units after electron beam sterilization, climatic conditioning, and distribution challenge conditioning.

Clinical Testing	Performance testing from clinical studies is not required to demonstrate substantial equivalence of OptiCross 35 15 MHz Peripheral Imaging Catheter.
Conclusion	Based on the indications for use, technological characteristics, and performance testing, OptiCross 35 15 MHz Peripheral Imaging Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to Atlantis PV Imaging Catheter, K080272.