January 17, 2018

Boston Scientific Corporation
Mugdha Dongre
Regulatory Affairs Specialist II
47215 Lakeview Boulevard
Fremont, California 94538

Re: K173820
Trade/Device Name: OptiCross 6 HD, 60 MHz Coronary Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: OBJ, ITX
Dated: December 15, 2017
Received: December 18, 2017

Dear Mugdha Dongre:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K173820

Device Name
OptiCross™ 6 HD, 60 MHz Coronary Imaging Catheter

Indications for Use *(Describe)*
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.

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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510(k) Summary per 21 CFR 807.92

Submitter's Name and Address	Boston Scientific Corporation 47215 Lakeview Boulevard Fremont, CA 94538 USA		
Contact Name and Information	Mugdha Dongre Regulatory Affairs Specialist II Tel: 510.624.1314 Fax: 510.440.7698 Email: Mugdha.Dongre@bsci.com		
Date Prepared	December 15, 2017		
Trade Name	OptiCross™ 6 HD, 60MHz Coronary Imaging Catheter		
Common Name	Diagnostic Intravascular Catheter, Ultrasound Transducer		
Classification Name	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 Name	OptiCross™ 6 40 MHz Coronary Imaging Catheter	K153617	25-Feb-2016
Reference Devices	OptiCross™ 18, 30 MHz Peripheral Imaging Catheter	K160514	22-June-2017
	OptiCross™, 40 MHz Coronary Imaging Catheter	K123621	15-April-2013
	OptiCross™ X, 40 MHz Coronary Imaging Catheter	K161125	19-May-2016
	OptiCross™ HD, 60 MHz Coronary Imaging Catheter	K173284	16-Nov-2017
Device Description	OptiCross™ 6 HD (60 MHz Coronary Imaging Catheters) 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 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™). 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 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.
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.
Device Technology Characteristics and Comparison to Predicate Device	The OptiCross™ 6 HD, catheter is a 60 MHz ultrasound coronary imaging catheter intended to operate with a BSC IVUS system for diagnostic imaging. It will be used with a minimum 6F (>0.064" ID) guide catheter / introducer sheath and a 0.014" guidewire. The OptiCross™ 6 HD Coronary Imaging Catheter incorporates a transducer with new design features intended to utilize a 60MHz frequency to enhance image resolution while maintaining similar depth of penetration as well as similar performance characteristics as that of its predicate OptiCross™ 6 40Mhz Coronary Imaging Catheter. Modifications with respect to the predicate device include:

	• A new transducer (new design with new materials) • PCA board populated with two zero Ohm resistors to generate DC coupling. In support of a substantial equivalence determination, BSC has compared and evaluated the material and design differences between the subject and predicate device. Non-clinical performance evaluations, as described below, indicate that the subject device is substantially equivalent to, and at least as safe and effective as the predicate device OptiCross™ 6, 40 MHz Coronary Imaging Catheter (K153617).
Non-Clinical Performance Data	Determination of substantial equivalence is based on an assessment of non-clinical performance data. Non-clinical data includes bench-top performance testing, packaging validation, biological safety, electromagnetic compatibility, acoustic output testing, and a GLP pre-clinical animal study to validate imaging performance in the porcine model. <u>Bench Testing:</u> Bench testing was performed to evaluate physical integrity, functionality, and overall performance of the catheter. Performance criteria includes deliverability, crossability, guide catheter compatibility, lubricity, retraction capability, image resolution, image penetration, non-uniform rotational distortion (NURD), measurement accuracy, pullback reliability, dimensional requirements, visibility under fluoroscopy, interface with ancillary devices, environmental requirements, user interface requirements, catheter robustness and simulated use structural integrity. <u>Pre-clinical Evaluation:</u> The purpose of this study was to support design validation and business need evaluations claims associated with *in-vivo* image quality. <u>Biological Safety Testing:</u> OptiCross™ 6 HD catheter utilizes existing materials from the commercially available OptiCross™ family of catheters which have similar configurations and are manufactured under the same processing conditions. Hence the biocompatibility test data has been leveraged from the commercially available OptiCross™ 6 and OptiCross™ 18 Imaging Catheter to meet the requirements of ISO 10993-1.

	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 (September 9, 2008).* Acoustic Output test results for OptiCross™ 6 HD are below the FDA Track 1 limits. Electromagnetic compatibility testing was also conducted; demonstrating compliance to IEC 60601-1-2 (3rd Edition). Packaging Validation: Packaging of OptiCross™ 6 HD catheters is equivalent to the packaging of other commercially available BSC IVUS catheters in the OptiCross™ product family. Thus, the OptiCross™ HD packaging will leverage the packaging DV results of the currently available OptiCross catheters to demonstrate it meets the required product specifications. Conclusion: Non-clinical performance evaluations, as described above, indicate that the subject device is substantially equivalent to, and at least as safe and effective as the predicate device, OptiCross™ 6, 40 MHz Coronary Imaging Catheter (K153617).
Clinical Performance Data	Not applicable; determination of substantial equivalence is based on an assessment of non-clinical performance data.
Conclusion	With respect to the predicate, design modifications incorporated by OptiCross™ 6 HD do not alter the fundamental scientific technology or the indications for use. Based on Failure Mode Effects Analysis (FMEA), comprehensive verification and validation activities were successfully completed; raising no new issues of safety or effectiveness. Non-clinical performance data supports a determination that the subject device, OptiCross™ 6 HD, is substantially equivalent to the predicate device, OptiCross™ 6, 40 MHz Coronary Imaging Catheter (K153617); and that it is at least as safe and effective for its intended use.