



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

May 19, 2016

Boston Scientific Corporation  
Eric Elliott  
Principal Regulatory Affairs Specialist  
47215 Lakeview Boulevard  
Fremont, California 94538

Re: K161125

Trade/Device Name: OptiCross™ X, 40 MHz Coronary Imaging Catheter  
Regulation Number: 21 CFR 870.1200  
Regulation Name: Diagnostic Intravascular Catheter  
Regulatory Class: Class II  
Product Code: OBJ, ITX  
Dated: April 20, 2016  
Received: April 21, 2016

Dear Eric Elliott:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

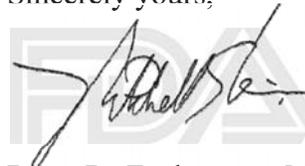
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

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

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K161125

Device Name  
OptiCross™ X  
40 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.

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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**Section 7                    510(k) Summary per 21 CFR 807.92**

<b>Submitter's Name and Address</b>	Boston Scientific Corporation 47215 Lakeview Boulevard Fremont, CA 94538		
<b>Contact Name and Information</b>	Eric Elliott Principal Regulatory Affairs Specialist Tel: 510.624.1314 Fax: 510.440.7698 E-mail: <a href="mailto:Eric.Elliott@bsci.com">Eric.Elliott@bsci.com</a>		
<b>Date Prepared</b>	April 20, 2016		
<b>Trade Name</b>	OptiCross™ X 40 MHz Coronary Imaging Catheter		
<b>Common Name</b>	Diagnostic Intravascular Catheter, Ultrasound Transducer		
<b>Classification Name</b>	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.		
<b>Predicate Device</b>	OptiCross™ 6 Coronary Imaging Catheter	K153617	25-Feb-2016
<b>Reference Device</b>	OptiCross™ Coronary Imaging Catheter	K123621	15-Apr-2013
<b>Description of Device</b>	<p>OptiCross™ X is a short-rail 40 MHz IVUS imaging catheter. It is compatible with a 0.014" guidewire, and at a minimum, a 5F guide catheter (≥ 0.058" ID).</p> <p>OptiCross X is intended for use with Boston Scientific's (BSC)'s iLab™ equipment and BSC's latest motor drive unit, MDU5 PLUS™. When used together, the catheter, motor drive unit (MDU), and iLab equipment form a complete imaging system that allows for ultrasonic examination of coronary intravascular pathology.</p> <p>The catheter consists of two main components: the catheter body and the imaging core.</p>		

**Device  
Description,  
continued**

The catheter body consists of four sections: the telescope assembly, proximal shaft, distal shaft, and the distal guidewire lumen. The proximal shaft, distal shaft, and distal guidewire lumen comprise the usable length of the catheter (135 cm). The proximal telescoping section remains outside of the guide catheter.

The distal guidewire lumen (1.6 cm) is used to track the catheter along the guidewire and incorporates a radiopaque marker band (0.5 cm from the distal tip). The distal shaft serves as a flexible and acoustically transparent imaging window. The proximal shaft provides pushability to the catheter and serves as a lumen to the imaging core. Two insertion markers are located on the proximal shaft (90 and 100 cm from the distal tip). These markers facilitate estimation of catheter position relative to the distal tip of the guide catheter.

The telescope assembly allows the imaging core to be advanced and retracted up to 15 cm. The corresponding movement of the transducer occurs within the imaging window from 2 to 17 cm from the distal tip of the catheter. The telescoping shaft includes 16 incremental markers (1 cm apart) for lesion length assessment; the 5-cm, 10-cm, and 15-cm markers are distinct. The outer surface of the catheter body also employs a hydrophilic coating to enhance lubricity and promote deliverability (distal 23 cm).

The imaging core consists of a proximal hub assembly and a rotating drive cable that houses a piezoelectric (PZT) transducer at the distal imaging window. The hub assembly (1) provides an electro-mechanical interface between the catheter and the motor drive unit and (2) incorporates a one-way check valve that is used to flush the interior of the catheter body. The catheter must be flushed with heparinized saline prior to use, as this provides the acoustic coupling media required for ultrasonic imaging.

The drive cable and PZT transducer rotate independently of the sheath to provide 360° image resolution. The transducer converts electrical impulses sent by the motor drive in to 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 visualization.

**Intended  
Use/Indications  
for Use**


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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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**Device  
Technology  
Characteristics  
and  
Comparison to  
Predicate  
Device**

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OptiCross™ X maintains the same fundamental scientific technology and operating principles as the predicate OptiCross™ 6 (K153617). Furthermore, sheath/imaging materials, device packaging, sterilization, ancillary capital equipment, and indications for use remain unchanged.

With narrowed proximal sheath and imaging window profiles, OptiCross X offers physicians a smaller 5F compatible alternative, while providing the same level of safety and performance of OptiCross 6 (6F compatible device). In practice, OptiCross X serves as the next iteration of BSC's legacy 5F guide catheter compatible platform, OptiCross™ (K123621).

Aside from the narrowed proximal sheath and imaging window profile, the only remaining difference between subject and predicate is the use of silicone for the anchor seal O-ring (telescope assembly); the same material employed by the legacy reference device OptiCross™ (K123621). With this one exception, all raw materials utilized by OptiCross™ X are identical to those of the predicate, OptiCross™ 6 (K153617).

In support of a substantial equivalence determination, BSC has compared and evaluated the 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, K153617).

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**Non-Clinical  
Performance  
Data**

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

Non-clinical data includes 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 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), image artifact, 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.

Biological Safety Testing:

OptiCross™ X was subjected to a series of biocompatibility tests in accordance with ISO 10993-1, microbial assessments including bioburden and endotoxin, pyrogenicity, and sterility assurance.

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 results for OptiCross™ X are below the FDA Track 1 limits. Electromagnetic compatibility testing was also evaluated; demonstrating compliance to IEC 60601-1-2 (3<sup>rd</sup> Edition).

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 subjected to electron beam sterilization, climatic conditioning, and distribution challenge conditioning.

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 (K153617).

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**Clinical  
Performance  
Data**

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

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**Conclusion**

With respect to the predicate, design modifications incorporated by OptiCross™ X 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™ X, is substantially equivalent to the predicate device, OptiCross™ 6 (K153617); and that it is at least as safe and effective for its intended use.

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