Section 9.0 510(k) Summary

Submitted by: Boston Scientific Corporation
47900 Bayside Parkway
Fremont, CA 94538

Contact: Emilly Tojima Nurthen
Regulatory Affairs Manager
47900 Bayside Parkway
Fremont, CA 94538
(510) 624-2546

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Trade Names: iCross™ Coronary Imaging Catheter
Atlantis™ SR Pro^2, Coronary Imaging Catheter

Common Names/Classification:
Diagnostic Intravascular Catheter, 21 CFR 870.1200 (OBJ)
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570 (ITX)

Predicate Devices: iCross ™ Coronary Imaging Catheter
Atlantis™ SR Pro^2 Coronary Imaging Catheter
K063312, cleared on November 30, 2006

Device Description:
The Catheters are sterile, single use, short rail (SR) 40MHz imaging catheters. These catheters are intended to operate with the BSC ClearView Ultra, Galaxy, Galaxy2, or iLab intravascular ultrasound imaging consoles. The coronary imaging catheter and console form an imaging system for ultrasonic examination of coronary intravascular pathology.

The Catheters consist of two (2) main assemblies: a sheath assembly and an imaging core assembly. The sheath assembly is the outer part of the catheter that comprises much of the working length of the device, and has a hydrophilic coating to the distal 230mm on the catheter. The imaging core is internal to the sheath assembly and rotates independently of the sheath. The imaging core contains the piezoelectric transducer that converts electrical energy from the imaging console to ultrasonic energy that is in turn transmitted. The transducer converts the returned ultrasonic energy into electrical energy for display on the instrument. The rotating imaging core driveshaft directs the path of the ultrasonic energy (beam) from the transducer. A proximal telescoping section allows the

imaging core to be retracted and advanced, across an anatomical region of interest, without requiring movement of the sheath within the anatomy.

Intended Use/Indications for Use:
The iCross™ and Atlantis™ SR Pro^2 Coronary Imaging Catheters are intended for ultrasound examination of coronary intravascular pathology only.
Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Predicate Device Comparison
The modified Catheter has the same design, materials, intended use and method of manufacture as the predicate device with the exception of product sterilization using Electron Beam (Ebeam) irradiation instead of Gamma irradiation in the currently marketed Catheters.

Non-Clinical Test Results
Bench and biocompatibility testing, in addition to a sterilization validation were conducted to demonstrate the modified iCross and Atlantis SR Pro^2 Coronary Imaging Catheters meet performance requirements and are substantially equivalent to the predicate devices.

Bench Testing
Bench testing was conducted to evaluate if the modified iCross and Atlantis SR Pro^2 catheters continue to meet product specifications post Ebeam sterilization. This evaluation consisted of performance, visual inspections, electrical and mechanical tests, of which the results demonstrated the devices satisfy all functional and physical requirements.

Acoustic output testing was conducted in accordance with the FDA Guidance *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers* (Sept 9, 2008) and the results continue to be below the Track 1 acoustic output exposure levels.

Biocompatibility
The modified iCross and Atlantis SR Pro^2 Coronary Catheters were tested for biocompatibility and the results demonstrate the devices are considered biocompatible for their intended use.

Sterilization
The sterilization validation confirmed Ebeam irradiated iCross and Atlantis SR Pro^2 Coronary Imaging Catheters continue to meet a Sterility Assurance Level (SAL) of 10^{-6}.

Conclusion
The testing conducted on the modified Catheters demonstrates they continue to meet performance requirements and are safe and effective for their intended use. The modified

iCross and Atlantis SR Pro^2 Coronary Imaging Catheters have the same intended use as the predicate and the test results support a determination of substantial equivalence to the currently marketed Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Boston Scientific Corporation
c/o Emilly Tojima Nurthen
Regulatory Affairs Manager
47900 Bayside Parkway
Fremont, CA 94538

AUG - 4 2011

Re: K111043/S001
Trade/Device Name: iCross™ and Atlantis™ SR Pro2 Coronary Imaging Catheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheters
Regulatory Class: Class II (two)
Product Code: OBJ, ITX
Dated: July 8, 2011
Received: July 11, 2011

Dear Ms Tojima:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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: K 11 1043

Device Names: iCross™ Coronary Imaging Catheter, Atlantis™ SR Pro^2 Coronary Imaging Catheter

Indications for Use:

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Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111043