K063312

Boston Scientific

NOV 3 0 2006

510(k) Summary of Safety and Effectiveness

Boston Scientific Corporation

Atlantis™ SR Pro 2 Coronary Imaging Catheter

Atlantis™ SR Pro Coronary Imaging Catheter

Submitted By: Boston Scientific Corporation
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538

Contact Person: Robert Z. Phillips
Manager, Regulatory Affairs
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Date Prepared: October 31, 2006

Proprietary Name(s): Atlantis™ SR Pro 2 Coronary Imaging Catheter
Atlantis™ SR Pro Coronary Imaging Catheter

Common Name(s): Ultrasound Diagnostic Imaging Catheter
Diagnostic Intravascular Catheter (74DQO)
Diagnostic Ultrasonic Transducer (90ITX)

Classification Name(s): Diagnostic Intravascular Catheters, 21 CFR 870.1200 (74DQO)
Diagnostic Ultrasonic Transducers, 21 CFR 892.1570 (90ITX)

Predicate Device(s): Atlantis™ SR Pro 2 and SR Pro Coronary Imaging Catheters are substantially equivalent to the following device(s):

Predicate	510(k)	Clearance Date
Atlantis™ SR Pro 2 Coronary Imaging Catheter (submission also covers SR Pro)	K050577	March 30, 2005

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Scientific Corp.
c/o Robert Phillips
Manager, Regulatory Affairs
47900 Bayside Parkway
Fremont, CA 94538

NOV 3 0 2006

Re: K063312
Trade/Device Name: Atlantic SR Pro.2 Coronary Imaging Catheter, Atlantis SR Pro Coronary Imaging Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: II
Product Code: DQO, ITX
Dated: November 1, 2006
Received: November 2, 2006

Dear Mr. Phillips:

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 such 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.

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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-__ (see bottom for #s). Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochnes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Boston Scientific

Indications for Use Statement

510(k) Number: K063312

Device Name: Atlantis™ SR Pro 2 Coronary Imaging Catheter

Indications for Use: The Atlantis™ SR Pro 2 Coronary Imaging 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.

Prescription Use___X___ OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063312