K050863
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510(k) Summary per 21 CFR §807.92

SEP 0 2 2005

Submitter's Name and Address	**Boston Scientific Corporation (BSC)** Two Scimed Place Maple Grove, MN 55311
Contact Name and Information	**Diane Brinza** Specialist, Regulatory Affairs Phone: 763-694-3061 Fax: 763-694-6966 e-mail: brinzad@bsci.com
Date Prepared	**April 4, 2005**
Proprietary Name(s)	Imager II Angiographic Catheters
Common Name	**Diagnostic Intravascular Catheter**
Product Code	**DQO**
Classification of Device	**Class II, 21 CFR Part 870.1200**
Predicate Device	**Imager™ II Angiographic Catheter** K011664 9/07/2001 K022621 9/04/2002
Device Description	The Imager II Angiographic Catheters are sterile, single-use diagnostic intravascular catheters. These catheters are available in a variety of flush and selective shapes with lengths of 40 cm, 65 cm, 90 cm and 100 cm. The distal segment of the catheter is radiopaque to aid in visualization of the device under fluoroscopy. Clinically, flush catheters are used to deliver a bolus of contrast to a patient when obtaining an image of a large area (aorta, leg-run off, etc.). Side-holes are also added to disperse the contrast. Selective catheters are used to create images of specific areas of interest.
Intended Use of Device	The Imager II Angiographic Catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system including the carotid arteries.
Technological Characteristics	Same as currently marketed Imager II Angiographic Catheter cleared for marketing under K011664 (September 7, 2001) and K022621 (September 4, 2001).
Non-Clinical Test Summary	Same as currently marketed Imager II Angiographic Catheter cleared for marketing under K011664 (September 7, 2001) and K022621 (September 4, 2001).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 2 2005

Boston Scientific Corporation
c/o Ms. Diane Brinza
Regulatory Affairs Specialist
One Boston Scientific Pl.
Natick, MA 01760

Re: K050863
Imager™ II Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheters
Regulatory Class: Class II
Product Code: DQO
Dated: August 22, 2005
Received: August 23, 2005

Dear Ms. Brinza:

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.

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); 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) 276-0120. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

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 (if known): K050863

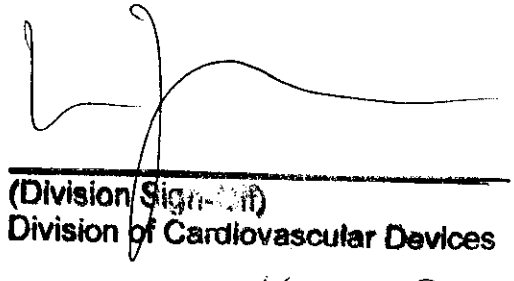
Device Name: Imager™ II Angiographic Catheter

Indications For Use: The Imager II Angiographic Catheters are designed to provide a pathway for delivering contrast media to selected sites in the vascular system including the carotid arteries

Prescription Use ___X___ AND/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)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K050863