MAR 2 9 2012

510(k) Summary

per 21 CFR §807.92

Sponsor:	Boston Scientific Corporation One Boston Scientific Place Natick MA 01760
Contact Person:	Anne Rossi
Phone Number:	763-255-0681
Fax Number:	763-494-2222
Prepared:	22 March 2012
Trade Name:	Imager™ II Angiographic Catheter
Common Name:	Diagnostic Intravascular Catheter
Classification:	II
Product Code:	DQO / 21 CFR 870.1200
Predicate Device:	Imager II Angiographic Catheter (K050863; 02 September 2005)

Device Description:

The 4F and 5F 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 added to disperse the contrast. Selective catheters are used to create images of specific areas of interest.

Intended 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.

Substantial Equivalence:

The modified Imager II Angiographic Catheter packaging configuration is substantially equivalent to the Imager II Angiographic Catheter (K050863, cleared 02 September 2005) packaging configuration.

Summary of Non-Clinical Testing:

Design verification testing as listed below was performed to verify the performance of the Imager II Angiographic Catheter packaging after multiple sterilization, climatic conditioning and distribution simulation conditioning is substantially equivalent to the predicate device.

- Visual Inspection
- Dye Penetration Testing
- Peel Testing
- Catheter Removal Force Testing

Summary of Clinical Testing:

Clinical Evaluation was not required for these devices.

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

MAR 2 9 2012

Boston Scientific Corp.
c/o Ms. Anne Rossi
Manager, Regulatory Affairs
One Scimed Place
Maple Grove, MN 55311-1566

Re: K120893
Trade/Device Name: Imager II Angiographic Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (two)
Product Code: DQO
Dated: 22 March, 2012
Received: 22 March, 2012

Dear Ms. Rossi:

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 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,

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): K120893

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 K120893