



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

October 29, 2015

Boston Scientific Corporation
Mac McKeen
Fellow, Regulatory Affairs
One Scimed Place
Maple Grove, MN 55311

Re: K152605

Trade/Device Name: Impulse™ and Expo™ Angiographic Guide Catheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Dated: October 12, 2015
Received: October 13, 2015

Dear Mr. Mac McKeen:

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" (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 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 Zuckerman". The signature is written in a cursive style and is positioned above the typed name.

for

Bram Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K152605

Device Name: Impulse™ and Expo™ Angiographic Catheter

Indications for Use:

The Impulse™ and Expo™ Angiographic Catheters are designed to provide a pathway to be used for delivering contrast media to selected sites in the vascular system during an angiographic procedure.

Prescription Use (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 In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) _____

510(k) Summary

per 21 CFR §807.92

Sponsor: Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA

Contact Person: Mac McKeen, mac.mckeen@bsci.com

Phone Number: 763-494-1409 Fax: 763-494-2222

Prepared: 10 September 2015

Trade Name: Impulse™ and Expo™ Angiographic Catheter

Common Name: Diagnostic Intravascular Guide Catheter

Classification: II

Product Code: DQO, 21 CFR 870.1200

Predicate Device: Impulse: K120495 (21 May 2012) Expo: K120495 (21 May 2012)

Device Description:

The Impulse™ and Expo™ Angiographic Catheters are single lumen catheters offered in three distal curve shapes: Selective, Pigtail and Multi-Purpose. The Expo Catheter is offered in 5F, 6F, and 7F outer diameter, and the Impulse Catheter is offered in 5F and 6F outer diameter. The device shafts have multiple polymer layers with a stainless steel braid embedded between the layers, and an atraumatic tip that does not contain a braid. The proximal end consists of an insert molded polymer hub on all models, and a strain relief on all models except the 7F Expo.

Intended Use

The Impulse™ and Expo™ Angiographic Catheters are intended for use in general intravascular applications to provide a pathway through which contrast media may be introduced.

Substantial Equivalence

Modified Impulse™ and Expo™ Angiographic Catheter designs, materials, manufacturing processes and intended use are substantially equivalent to the predicate Impulse™ and Expo™ Angiographic Catheters.

Summary of Non-Clinical Testing

Design verification testing, including mechanical bench testing was performed to verify that the performance of the proposed Impulse™ and Expo™ Angiographic Catheters remain substantially equivalent to the predicate devices. Biocompatibility, sterility, and packaging testing were also performed to verify the overall safety and efficacy of the device.

Specifically the following design verification was performed:

- Shaft Integrity: Burst Pressure
- Hub Leakage
- Tensile Test
- Gauging Test
- Liquid Leakage
- Air Leakage
- Unscrewing Torque
- Ease of Assembly
- Stress Cracking
- Biocompatibility Testing
 - Cytotoxicity
 - Hemolysis
 - Inductively Coupled Plasma – Mass Spectrometry (ICP-MS)
 - FTIR
 - Nonvolatile Residue (NVR)

Summary of Clinical Testing

Clinical Evaluation was not required for these devices.