



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Boston Scientific Corporation
% Mr. George J. Prendergast
Senior Regulatory Affairs Specialist
47215 Lakeview Blvd.
FREMONT CA 94538

September 18, 2015

Re: K152316
Trade/Device Name: iLab™ Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: August 17, 2015
Received: August 18, 2015

Dear Mr. Prendergast:

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” (21 CFR 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 blue ink that reads "Michael D. O'Hara". The signature is written over a faint, large watermark of the FDA logo.

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152316

Device Name

iLab Ultrasound Imaging System

Indications for Use (Describe)

The iLab Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated for patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Boston Scientific Corporation
iLab Ultrasound Imaging System

This 510(k) Summary is provided in this Premarket Notification in accordance with requirements of the Safe Medical Device Act (SMDA) of 1990. The content is submitted in conformance with 21 CFR Part 807.92.

Submitted By: Boston Scientific Corporation
47215 Lakeview Blvd.
Fremont, CA. 94538

Contact Person: George J. Prendergast
Senior Regulatory Affairs Specialist
Tel: 510-624-1634
George.Prendergast@bsci.com

Date: Prepared: August 14, 2015

Proprietary Name: iLab™ Ultrasound Imaging System

Common Name: Ultrasound Diagnostic Imaging System/
Ultrasonic Pulsed Echo Imaging System (90IYO)
Transducer, Ultrasonic, Diagnostic (90ITX)

Classification Name: Class II
Ultrasonic Pulsed Echo Imaging System
21 CFR Part 892.1560 (90IYO)
Transducer, Ultrasonic, Diagnostic
21 CFR Part 892.1570 (90ITX)
Radiology/Cardiology Panel

Product Code: 90IYO, 90ITX

Boston Scientific Corporation
Special 510(k)
iLab Ultrasound Imaging System

Predicate Device: iLab™ Ultrasound Imaging System

Product	510(k)	Clearance Date
iLab Ultrasound Imaging System	K130243	March 1, 2013

Description of the Device:

iLab Ultrasound Imaging System

The iLab Ultrasound Imaging System is designed for real time viewing of intravascular anatomies and is intended to be a basic diagnostic tool for imaging and evaluation of patients who are candidates for transluminal procedures.

Permanent Pullback Sled

The Permanent Pullback Sled is a device which is used with the iLab Ultrasound Imaging System. The permanent sled is a mechanized device to assist with the acquisition of two-dimensional images obtained from compatible Boston Scientific intravascular ultrasound imaging catheters. This device is designed to be used with Boston Scientific IVUS catheters that have telescoping capability where the catheter anchor housing can engage in the anchor post of the sled.

Intended Use / Indications For Use:

The iLab Ultrasound System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy. The intended use/indications for use are identical to the predicate device

Technological Characteristics:

The modified iLab Ultrasound Imaging System employs the same Indications for Use, fundamental scientific technology, and principle of operation as its predicate device.

There are similarities and differences between the materials used in the proposed Permanent Pullback Sled in comparison to the Disposable Pullback Sled.

Boston Scientific Corporation
Special 510(k)
iLab Ultrasound Imaging System

Design verification testing and packaging testing were performed on the permanent sled. The passing results of testing demonstrate the device is safe and effective and do not raise different questions of safety and effectiveness than the predicate.

Determination of Substantial Equivalence: Non-Clinical Data

Determination of substantial equivalence is based in part on an assessment of non-clinical performance data. Non-clinical data included design verification of the proposed non-sterile, permanent sled. All predetermined acceptance criteria were met during design verification as specified in the requirements of 21 CFR 820.30. The design verification testing results did not raise different questions of safety and effectiveness associated with changes made to the device.

Bench/Performance Testing

Design verification testing included the following tests which passed based on a Pass/Fail basis: Motordrive Pullback, Force to Open Latch, Motordrive/Pullback Sled Connection, Linear Velocity, Cleaning Materials Exposure, Acoustic Noise, Holding Force of Nose Section to Anchor Seal, Sled Travel Distance, Nose Clip Insertions, Sled Pullbacks, and environmental requirements.

Packaging Validation

The permanent sled packaging integrity was tested on fully packaged units after being subjected to climactic conditioning and distribution challenge conditioning. Testing included Visual Inspection and functional testing.

Non Clinical Testing Conclusion

The non-clinical testing demonstrates the proposed device is as safe and as effective and performs as well as or better than the legally marketed device.

Clinical Data / Animal Data:

No clinical or animal data were generated to support this submission.

Conclusion:

The proposed modifications to the iLab Ultrasound Imaging System described in this submission are substantially equivalent to the predicate device. The proposed modification of the iLab Imaging System and labeling are not substantial changes. They do not significantly affect the safety and efficacy of the device.