



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 26, 2016

Boston Scientific Corporation
Eric Elliott
Principal Regulatory Specialist
47215 Lakeview Boulevard
Fremont, California 94538

Re: K160173

Trade/Device Name: Ultra ICE Plus 9 MHz IntraCardiac Echo Catheter
Regulation Number: 21 CFR 870.2330
Regulation Name: Echocardiograph
Regulatory Class: Class II
Product Code: DXK, ITX
Dated: January 22, 2016
Received: January 27, 2016

Dear Eric Elliott:

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

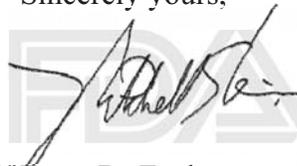
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

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) K160173

Device Name

Ultra ICE™ Plus

9 MHz IntraCardiac Echo Catheter

Indications for Use (Describe)

The Ultra ICE Plus rounded tip catheter is indicated for enhanced ultrasonic visualization of intracardiac structures.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 7 510(k) Summary per 21 CFR 807.92

Submitter's Name and Address	Boston Scientific Corporation 47215 Lakeview Boulevard Fremont, CA 94538		
Contact Name and Information	Eric Elliott Principal Regulatory Affairs Specialist Tel: 510.624.1314 Fax: 510.440.7698 E-mail: Eric.Elliott@bsci.com		
Date Prepared	January 22, 2016		
Trade Name	Ultra ICE™ Plus 9 MHz IntraCardiac Echo Catheter		
Common Name	Echocardiograph, Ultrasound Transducer		
Classification Name	Ultrasound, Echocardiograph (DXK) has been classified as Class II per 21 CFR 870.2330 Transducer Ultrasonic (ITX) has been classified as Class II per 21 CFR 892.1570.		
Predicate Device	Ultra ICE™ 9 MHz IntraCardiac Echo Catheter	K902245	9-Oct-1990
Description of Device	<p>Ultra ICE Plus is intended for use with Boston Scientific's (BSC)'s iLab™ equipment and latest motor drive unit, MDU5 PLUS™. When used together, the catheter, motor drive unit (MDU), and iLab equipment form a complete imaging system that allows for ultrasonic visualization of intracardiac structures.</p> <p>The catheter consists of two main components: the catheter body and the imaging core.</p> <p>The catheter body consists of three sections: the braided proximal shaft, single lumen mid-shaft, and the sonolucent distal tip. The catheter body comprises the usable length of the catheter (110 cm).</p>		

**Device
Description,
continued**

The braided proximal shaft provides pushability to the catheter and serves as a lumen to the imaging core. The mid-shaft provides a flexible transition between the stiffer proximal shaft and the acoustically transparent distal tip. The distal tip serves as the imaging window and houses a septum situated between the inner lumen and the atraumatic rounded tip of the catheter. The self-sealing septum serves as the distal-flush entry point; as the catheter must be flushed with water prior to use. This provides the acoustic coupling media required for ultrasonic imaging.

The imaging core consists of a proximal hub assembly and a rotating drive cable that houses a low frequency piezoelectric (PZT) transducer at the distal imaging window. The hub assembly provides an electro-mechanical interface between the catheter and the motor drive unit.

The drive cable and PZT transducer rotate independently of the sheath to provide 360° image resolution. The transducer converts electrical impulses sent by the motor drive in to transmittable acoustic energy. Reflected ultrasound signals are converted back to electrical impulses, returned to the motor drive unit, and are ultimately processed by the iLab equipment for live visualization of intracardiac structures.

**Intended
Use/Indications
for Use**

The Ultra ICE™ Plus rounded tip catheter is indicated for enhanced ultrasonic visualization of intracardiac structures.

**Device
Technology
Characteristics
and
Comparison to
Predicate
Device**

The Ultra ICE™ Plus 9 MHz IntraCardiac Echo Catheter maintains the same fundamental scientific technology and operating principles as the predicate Ultra ICE™ (K902245). Furthermore, the transducer, sheath design, and indications for use remain unchanged.

Modifications with respect to the predicate device include a new hub interface for compatibility with the MDU5 PLUS™ motor drive unit, potting adhesives aligned with current manufacturing processes, and replacement of a now obsolete resin (non-patient contacting component) that serves as strain relief between the distal housing and coax cable. In practice, Ultra ICE™ Plus is the drop-in replacement for BSC's mature Ultra ICE™ platform, but with the latest hub technology and compatibility with the MDU5 PLUS motor drive unit; as similarly adopted by the now prevalent OptiCross™ Coronary Imaging Catheter (K123621).

Finally, Ultra ICE™ Plus will be sterilized using electron beam (E-Beam) irradiation, not gamma as utilized by the predicate.

In support of a substantial equivalence determination, BSC has compared and evaluated the material and design differences between the subject and predicate device.

Non-clinical performance evaluations, as described below, indicate that the subject device is substantially equivalent to, and at least as safe and effective as the predicate device (Ultra ICE, K902245).

**Non-Clinical
Performance
Data**

Determination of substantial equivalence is based on an assessment of non-clinical performance data.

Non-clinical data includes bench-top performance evaluations, packaging validation, biological safety, electromagnetic compatibility, and acoustic output testing.

Bench Testing:

Bench testing was performed to evaluate physical integrity, functionality, and performance of the catheter. Performance criteria includes deliverability, guide catheter compatibility, image quality, non-uniform rotational distortion, measurement accuracy, general imaging capabilities, dimensional requirements, visibility under fluoroscopy, interface with ancillary devices, environmental requirements, user interface requirements, and catheter fatigue and bending stiffness when prepped and used per the DFU.

Biological Safety Testing:

Ultra ICE™ Plus was subjected to a series of biocompatibility tests in accordance with ISO 10993-1, microbial assessments including bioburden and endotoxin, pyrogenicity, and sterility assurance.

Electrical and Mechanical Safety:

Acoustic Output was evaluated in accordance with FDA Guidance, *Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008)*. Acoustic Output test results for the Ultra ICE™ Plus are below the FDA Track 1 limits. Electromagnetic compatibility testing was also conducted; demonstrating compliance to IEC 60601-1-2 (3rd Edition).

Packaging Validation:

The integrity of the packaging configuration was evaluated in accordance with ISO 11607-1 and ISO 11607-2. Testing was conducted on fully packaged units after subjected to electron beam sterilization, climatic conditioning, and distribution challenge conditioning.

Conclusion:

Non-clinical performance evaluations, as described above, indicate that the subject device is substantially equivalent to, and at least as safe and effective as the predicate device, Ultra ICE™ (K902245).

**Clinical
Performance
Data**

Not applicable; determination of substantial equivalence is based on an assessment of non-clinical performance data.

Conclusion

With respect to the predicate, design modifications incorporated by Ultra ICE™ Plus do not alter the fundamental scientific technology or the indications for use. Based on Failure Mode Effects Analysis (FMEA), comprehensive verification and validation activities were successfully completed; raising no new issues of safety or effectiveness.

Non-clinical performance data supports a determination that the subject device, Ultra ICE™ Plus, is substantially equivalent to the predicate device, Ultra ICE™ (K902245); and that it is at least as safe and effective for its intended use.
