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

October 21, 2015

Boston Scientific Corporation
Maylin Truesdell
Senior Regulatory Affairs Specialist
55 Technology Dr.
Lowell, Massachusetts 01851

Re: K152693
Trade/Device Name: Clearsign II Amplifier
Regulation Number: 21 CFR 870.2060
Regulation Name: Transducer Signal Amplifier and Conditioner
Regulatory Class: Class II (Two)
Product Code: DRQ
Dated: September 18, 2015
Received: September 21, 2015

Dear Maylin Truesdell:

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.

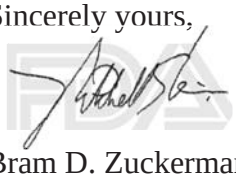
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 2: Indications for Use Statement

Indications for Use

510(k) Number (if known): K152693

Device Name: CLEARSIGN II Amplifier

Indications for Use:

The CLEARSIGN II Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the LabSystem PRO EP Recording System) that can record and display the information.

Contraindications: None

Prescription Use __X___		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(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)

Attachment 3: 510(k) Summary

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation 55 Technology Drive Lowell, MA 01851 Phone: 978-805-3231 Fax: 978-805-3281
Contact Name and Information	Maylin Truesdell Senior Regulatory Affairs Specialist Phone: 978-805-3231 Fax: 978-805-3281 E-mail: maylin.truesdell@bsci.com
Date Prepared	September 09, 2015
Proprietary Name	CLEARSIGN II Amplifier
Model Numbers	M00420020210 CLEARSIGN II Amplifier, 40 channels M00420020220 CLEARSIGN II Amplifier, 80 channels M00400202300 CLEARSIGN II Amplifier, 120 channels M00420020240 CLEARSIGN II Amplifier, 160 channels
Common Name	Transducer Signal Amplifier and Conditioner
Product Code	DRQ - Transducer Signal Amplifier and Conditioner
Classification	Class II, 21 CFR Part 870.2060
Predicate Devices	**CLEARSIGN II Amplifier** Kl50235, cleared April 22, 2015
Device Description	The LabSystem Pro (LS PRO) EP Recording System (K141185) with CLEARSIGN/CLEARSIGN II Amplifier is an integrated system that acquires, displays, records, and measures physiological signals that originate from that heart. The CLEARSIGN II Amplifier is a reusable electromedical device containing hardware and software that acquires, conditions and presents the physiological signal to the LabSystem PRO EP Recording System such that the signals are available for clinical user selection, display and recording. The CLEARSIGN II Amplifier is used in conjunction with the compatible diagnostic electrophysiology (EP) catheters, surface ECG leads, intravascular pressure transducers, intracardiac stimulators, RF ablation generators and cardiac ablation catheters. The CLEARSIGN II Amplifier is intended for use during EP diagnostic and therapeutic procedures in an EP cath lab.

Intended Use/ Indications for Use	The CLEARSIGN II Amplifier is intended to amplify and condition electrocardiographic signals of biologic origin and pressure transducer input, transmitting this information to a host computer (the LabSystem PRO EP Recording System) that can record and display the information.
Comparison of Technological Characteristics	The predicate device for this 510(k) Premarket Notification is the CLEARSIGN II Amplifier KI50235, cleared April 22, 2015. The Indications for Use between the predicate, CLEARSIGN II Amplifier, and the proposed device, CLEARSIGN II Amplifier, are identical. The CLEARSIGN II Amplifier incorporates fundamentally the same technological characteristics as the predicate device. The basic architecture and design of the hardware and software are the same; the only change is a single line of code in the CLEASIGN II firmware. Therefore, the CLEARSIGN II Amplifier is substantially equivalent to the predicate device.
Performance Data	Design verification testing was performed to support a determination of substantial equivalence. The CLEARSIGN II Amplifier is developed in accordance with 21 CFR 820.30 Quality System Regulation Design Controls. Testing conducted included: • CLEARSIGN II ECG Offset Test • Firmware version 2.09 Verification Testing • Software Verification Testing The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the device testing.
Conclusion	Based on the idential indications for use, substantially equivalent technological characteristics, and safety and performance testing, the CLEARSIGN II Amplifier has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the CLEARSIGN II Amplifier KI50235, cleared April 22, 2015.