DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 22, 2015

Boston Scientific Corporation
Maylin Truesdell, Senior Regulatory Affairs Specialist
Electrophysiology Division
55 Technology Drive
Lowell, MA 01851

Re: K150235
Trade/Device Name: CLEARSIGN II Amplifier, with models 2002021, 2002022, 2002023 and 2002024
Regulatory Number: 21 CFR 870.2060
Regulation Name: Transducer Signal Amplifier and Conditioner
Regulatory Class: Class II (Two)
Product Code: DRQ
Dated: March 23, 2015
Received: March 24, 2015

Dear Ms. 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.

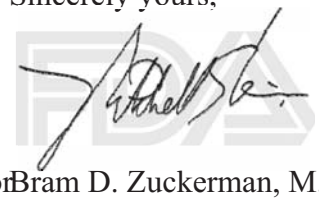
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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

Attachment 2: Indications for Use Statement

Indications for Use

510(k) Number (if known):_K150235_____

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	January 28, 2015
Proprietary Name	CLEARSIGN II Amplifier
Model Numbers	2002021 CLEARSIGN II Amplifier, 40 channels 2002022 CLEARSIGN II Amplifier, 80 channels 2002023 CLEARSIGN II Amplifier, 120 channels 2002024 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 (Borealis) Amplifier K050006, cleared May 27, 2005
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 (Borealis) Amplifier, K050006 cleared May 27, 2005. The Indications for Use between the predicate, CLEARSIGN 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 changes are to bring the equipment to state-of-the-art (specifically, compliance with IEC 60601-1, 3rd Edition), to comply with the EU RoHS Directive, and to implement minor performance improvements. Therefore, the CLEARSIGN II Amplifier is substantially equivalent to the predicate device.

Performance Data

Bench testing and *in vivo* testing were 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. The device was developed and tested in accordance with the following industry standards:

- IEC 60601-1, 3rd Edition, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 ed3.0 (2007-03), Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 62304:2006, Medical device software – Software life-cycle processes
- ISO 14971:2012, Medical devices - Application of risk management to medical devices

Testing conducted included:

- Electrical safety testing and assessment of risk management, in accordance with IEC 60601-1, 3rd Edition
- Electro-magnetic compatibility (emissions and immunity) testing, in accordance with IEC 60601-1-2, 3rd Edition
- Software verification and validation including software lifecycle assessment per ISO 62304 and FDA guidelines
- Drop/ship testing, per ISTA 2A requirements
- Testing of specific functions, including the invasive blood pressure function (per IEC 60601-2-34) and the electrocardiographic monitoring function (per IEC 60601-2-27)
- Operational temperature and atmospheric environment testing
- Testing for compatibility with the CARTO 3D navigation and mapping system (Biosense Webster, Diamond Bar, CA), as LabSystem PRO is labeled for use with CARTO
- *In vivo* animal testing

All testing met pre-defined acceptance criteria, thus confirming the safety and effectiveness of each functional aspect of the CLEARSIGN II Amplifier.

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 (Borealis) Amplifier as submitted in K050006.