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

July 6, 2017

Boston Scientific Corporation
Melissa Klamerus
Regulatory Specialist
4100 Hamline Ave North
St. Paul, Minnesota 55112

Re: K170815
Trade/Device Name: PSA Cable
Regulation Number: 21 CFR 870.3630
Regulation Name: Pacemaker Generator Function Analyzer
Regulatory Class: Class II
Product Code: DTC
Dated: March 16, 2017
Received: March 17, 2017

Dear Melissa Klamerus:

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,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170815

Device Name
PSA Cable

Indications for Use *(Describe)*
The PSA cable is an accessory indicated for use with external PSA equipment distributed by Boston Scientific and is used for the transmission of sensing signals and pacing pulses for evaluation of lead placement characteristics during implant of pacemakers and defibrillators and for the support of other pacemaker functionality

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.

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Boston Scientific

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510(k) Summary for PSA Cable, Model 6763

1. Submitter

Boston Scientific Corporation
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5798

Contact: Melissa Klamerus
Regulatory Affairs
Phone: (651) 582-6771
Email: Melissa.klamerus@bsci.com

Date Prepared: February 25, 2017

2. Device

Trade Name: PSA Cable
Common Name: PSA Cable
Product Code and Panel: DTC, Cardiovascular
Classification Regulation: 21 CFR 870.3630

3. Predicate Device

Trade Name: PK-141 Patient Cable (PSA Cable)
Manufacturer: Biotronik
Clearance Number: K083674, April 1 2009
Common Name: PSA Cable
Product Code: DTC
Device Class and Panel: Class II, Cardiovascular
Classification Regulation: 21 CFR 870.3630

4. Device Description

The Pacing System Analyzer (PSA) cable, Model 6763, is an external cable used to transmit signals to and from a connected PSA device. The connected PSA equipment is used during the implantation of pacemakers and defibrillators to evaluate the placement and integrity of leads and to determine the appropriate pacing parameters for the implanted device. The PSA cable leadwires are affixed to the implanted lead while the other end of the cable, the trunk cable, is plugged into the external PSA device. The PSA cable is used with the BSC distributed PSA devices.

The PSA cable leadwires may incidentally contact the patient's skin as they lay across the body while attached to the leads. Per ISO 10993-1, skin/body contact for this device is categorized as Limited (<24 hours). The trunk cable (including yoke, ferrite cylinder and instrument connector) is non-patient contacting.

5. Indication for Use

The PSA cable is an accessory indicated for use with external PSA equipment distributed by Boston Scientific and is used for the transmission of sensing signals and pacing pulses for evaluation of lead placement characteristics during implant of pacemakers and defibrillators and for the support of other pacemaker functionality.

6. Substantial Equivalence

Characteristic	BSC Model 6763 PSA Cable	Biotronik Model PK-141 PSA Cable
Indications for use	The PSA cable is an accessory indicated for use with external PSA equipment distributed by Boston Scientific and is used for the transmission of sensing signals and pacing pulses for evaluation of lead placement characteristics during implant of pacemakers and defibrillators and for the support of other pacemaker functionality.	The PK-141 cable is an accessory indicated for use with external equipment from Biotronik and is used for the transmission of sensing signals and pacing pulses for diagnosis and therapy in the context of intracardiac examinations including the following activities: temporary external pacing, lead threshold determination, and pacemaker function test.
Usage	Reusable	Reusable
Sterility	Supplied non-sterile/resterilizable	Supplied sterile/resterilizable
Functionality	transmit signals from 4 patient-connected leadwires	transmit signals from 4 patient-connected leadwires
Cable length	**Overall length:** ~ 112 inches **Trunk cable length:** 100 ± 6 inches **Leadwire length** (each) 2 – 9" ± 1 inch 2 – 12" ± 1 inch	**Overall length:** 2.8m (~110.2 inches) **Trunk cable length:** 2.5m (~ 98.4 in) **Leadwire length** (each) 2 – 0.23 m (~ 9 inches) 2 – 0.30 m (~11.8 inches)
Connectors	Alligator clip 6 pin push/pull	Alligator clip 6 pin push/pull
Packaging	• outer labeled box • inner bubble pouch/bag • non-sterile	• outer labeled box • inner sterile box • sterile

7. Performance Data

Design verification and validation (V&V) testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device design meets performance requirements and performs as intended.

Design verification and validation testing included:

- Sterilization
- Biocompatibility
- Electromagnetic compatibility
- Electrical safety
- Performance/Bench testing

8. Conclusion

Based on the indications for use, technological characteristics, and performance testing, the BSC PSA cable has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate cable.