



October 6, 2015

Boston Scientific Corporation
James Kleinedler
Senior Regulatory Affairs Specialist
47215 Lakeview Boulevard
Fremont, California 94538

Re: K151610
Trade/Device Name: Comet Pressure Guidewire
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II
Product Code: DXO, DQX
Dated: October 1, 2015
Received: October 2, 2015

Dear Dr. Kleinedler:

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,


Kenneth J. Cavanaugh -S

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

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

Indications for Use

510(k) Number (if known)

Device Name

Comet™ Pressure Guidewire

Indications for Use (Describe)

The Comet™ Pressure Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) SUMMARY

Proprietary Name: Comet™ Pressure Guidewire

Common Name: Pressure Guidewire

Classification Name: Transducer, Pressure, Catheter Tip
(per 21 CFR 870.2870)

Device Classification: Class II

Product Classification and Code: DXO, DQX

Classification Panel: Cardiovascular Devices

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Date Prepared: June 15, 2015

Performance Standards

Performance standards do not currently exist for this device. None are established under Section 514.

Device Description

Comet™ is a coronary and peripheral guidewire with a pressure sensor mounted approximately 3 cm proximally to the distal end of the straight tip. The optical pressure sensor is integrated within the distal region of a 0.014” guidewire to measure blood pressure gradient changes across coronary and peripheral lesions during endovascular procedures. The tip is radiopaque to help with guidewire placement and shapeable by the user. The guidewire is attached to an optical cable through a detachable connector. The optical cable has a connector on the proximal end for interface with an ancillary Boston Scientific signal-processing module. When connected to the signal-processing module, a Boston Scientific iLab Polaris™ Multi-Modality Guidance System displays various physiological parameters including aortic pressure, distal pressure and a fractional flow reserve (FFR) value calculated from the ratio of distal pressure over aortic pressure. A torque device is pre-loaded onto the proximal end of the wire. The pressure guidewire, optical cable, and torque device are all connected in the single use sterilized packaging. The intended use of Comet remains within the scope of the predicate intended use. The subject device features a narrower intended use (i.e., FFR) as compared to the PressureWire Certus (i.e., any physiological parameters). Narrower intended use does not raise new questions of safety and/or effectiveness.

Intended Use

The Comet™ Pressure Guidewire measures blood pressure gradient across coronary and peripheral lesions during endovascular procedures. FFR (Fractional Flow Reserve) pressure guidewire may also be used as a coronary or peripheral guidewire for interventional treatments.

Indications for Use

The Comet™ Pressure Guidewire is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels.

Substantially Equivalent Devices

The following predicate device is substantially equivalent to the subject device:

- St. Jude Medical PressureWire™ Certus™ K131452 (cleared September 5, 2013)

Brief Comparison Summary

To demonstrate substantial equivalence of the Boston Scientific Comet Pressure Guidewire to the predicate device, technological characteristics and performance criterion were evaluated using *in vitro* and *in vivo* testing as indicated below:

***In Vitro* Testing**

Using FDA guidance documents on non-clinical testing of medical devices the following *in vitro* tests were performed:

- Dimensional Verification
- Surface Evaluation
- Tensile Strength
- Torque Strength
- Torqueability
- Tip Stiffness
- Catheter Compatibility
- Fracture
- Flexing Test
- Coating Adherence/Integrity
- Particulate Evaluation
- Corrosion Resistance
- Tracking Force
- Tip Shape Retention
- Sensing Accuracy
- Sensing Drift
- Interface Challenge
- Package Integrity
- Sterility and EO Residuals
- Biocompatibility
- Endotoxin

***In Vivo* Testing**

To assess the acute performance of the Comet Pressure Guidewire in a vascular application, *in vivo* studies were conducted in GLP porcine model to assess pressure sensing accuracy and device thrombogenicity. Additionally, radiodetectability and measurement drift were evaluated in non-GLP porcine models.

The results from these *in vitro* and *in vivo* tests demonstrate that the technological characteristics and performance criteria of the Comet Pressure Guidewire are comparable to the predicate devices and that it can perform in a manner equivalent to devices currently on the market for the same intended use.

Conclusion (Statement of Equivalence)

As the indications for use and fundamental scientific technology have not changed, non-clinical performance data supports a determination that the subject device is substantially equivalent to the predicate device, and that it is at least as safe and effective for its intended use.