DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 14, 2014

Boston Scientific Corp.
Allison Baillie
Regulatory Affairs Specialist II
100 Boston Scientific Way
Marlborough, MA 01752

Re: K141820
Trade/Device Name: Jagwire™ High Performance Guidewire
Jagwire™ High Performance Extendable Guidewire
Jagwire™ High Performance Guidewire Extension
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: OCY
Dated: July 3, 2014
Received: July 7, 2014

Dear Allison Baillie,

This letter corrects our substantially equivalent letter of October 21, 2014.

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,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K141820

Device Name
Jagwire™ High Performance Guidewire, Jagwire™ High Performance Extendable Guidewire

Indications for Use *(Describe)*
Indicated for use in selective cannulation of the biliary ducts including, but not limited to the common bile, cystic, right and left hepatic ducts. The guidewires are designed to be used during endoscopic biliary procedures for catheter introduction and exchanges.

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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Food and Drug Administration
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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)*
K141820

Device Name
Jagtail™ High Performance Guidewire Extension

Indications for Use *(Describe)*
The Jagtail™ High Performance Guidewire Extension attached to the extendable Jagwire™ 260 cm Guidewire is designed for use during endoscopic biliary procedures for non-rapid exchange catheter introduction and exchanges. The attachment of the Jagtail High Performance Guidewire Extension to the extendable Jagwire 260 cm guidewire creates an extended guidewire that can be used to exchange out a non-rapid exchange biliary catheter without removing the original guidewire from the associated duct. When the exchange is completed, the Jagtail High Performance Guidewire Extension can be detached and the original, extendable Jagwire 260 cm guidewire can be used in a conventional manner.

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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SECTION 5
510(k) SUMMARY

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4942
Fax: 508-683-5939

Contact: Allison Baillie
Regulatory Affairs Specialist II
Date Prepared: October 17, 2014

2. Device

Trade Names:	Jagwire™ High Performance Guidewire, Jagwire™ High Performance Extendable Guidewire, Jagtail™ High Performance Guidewire Extension
Common Name:	Endoscopic Guidewire
Classification Name:	Endoscope and accessories
Regulation Number:	876.1500
Product Code:	OCY
Classification:	Class II

3. Predicate Devices

Trade Name:	Jagwire™ High Performance Guidewire, Jagwire™ High Performance Extendable Guidewire, Jagtail™ High Performance Guidewire Extension
Manufacturer and Clearance Number:	Boston Scientific Corporation, K960186
Common Name:	Endoscopic Guidewire
Classification Name:	Endoscope and accessories
Regulation Number:	876.1500
Product Code:	EZB, OCY
Classification:	Class II (previously 510(k) exempt under Procode EZB)

Trade Name:	Sensor Guidewire
Manufacturer and Clearance Number:	Boston Scientific Corporation, 510(k) Exempt
Common Name:	Endoscopic Guidewire
Classification Name:	Endoscope and accessories
Regulation Number:	876.1500
Product Code:	EZB
Classification:	Class II (previously 510(k) exempt under Procode EZB)

4. Device Description

Jagwire™ High Performance Guidewire, and Jagwire™ High Performance Extendable Guidewire:

The Boston Scientific Jagwire™ High Performance Guidewire is constructed of a metal alloy core, which is encapsulated in a striped PTFE jacket with a 5 cm hydrophilic radiopaque distal tip. The striped jacket provides endoscopically visible movement markings.

Jagtail™ High Performance Guidewire Extension:

The Boston Scientific Jagtail™ High Performance Guidewire Extension is a 200 cm long guidewire extension constructed of a stainless steel core with a connector at the distal end. The shaft is coated with a PTFE sleeve. The Jagtail High Performance Guidewire Extension is exclusively compatible with the Jagwire High Performance Extendable Guidewire, 260 cm. The distal end of the Jagtail High Performance Guidewire Extension is inserted into the proximal end of the extendable Jagwire 260 cm guidewire with the use of the alignment tool. The alignment tool is then removed from the Jagtail High Performance Guidewire Extension.

5. Indication for Use:

Jagwire™ High Performance Guidewire, and Jagwire™ High Performance Extendable Guidewire:

Indicated for use in selective cannulation of the biliary ducts including, but not limited to the common bile, cystic, right and left hepatic ducts. The guidewires are designed to be used during endoscopic biliary procedures for catheter introduction and exchanges.

Jagtail™ High Performance Guidewire Extension:

The Jagtail™ High Performance Guidewire Extension attached to the extendable Jagwire™ 260 cm Guidewire is designed for use during endoscopic biliary procedures for non-rapid exchange catheter introduction and exchanges. The attachment of the Jagtail High Performance Guidewire Extension to the extendable Jagwire 260 cm guidewire creates an extended guidewire that can be used to exchange out a non-rapid exchange biliary catheter without removing the original guidewire from the associated duct. When the exchange is completed, the Jagtail High Performance Guidewire Extension can be detached and the original, extendable Jagwire 260 cm guidewire can be used in a conventional manner.

6. Technological Characteristics:
The materials used to attach the Tungsten/Pebax tip of the proposed Jagwire™ Guidewires have changed slightly. The current adhesive primer material used to attach the current Jagwire guidewire tip has been discontinued by the supplier.

Two options for replacement a material for the discontinued adhesive primer material are proposed. One option is a direct replacement of the discontinued adhesive primer material. The second option is a material that is coextruded with the guidewire tip, which has also simplified the tip attachment process.

With the exception of the changes in the tip attachment materials, the proposed Jagwire™ guidewires are identical in design, materials and intended use to the currently commercialized Jagwire™ guidewires. There were no changes made to the Jagtail™ High Performance Guidewire Extension.

7. Performance Data:
Non-clinical testing was successfully performed on the proposed Jagwire™ Guidewires as described below.

Biocompatibility Testing Summary:
The proposed Jagwire Guidewires were assessed in accordance with ISO 10993-1, and are classified as surface, limited contact duration (<24hours), mucous membrane contact devices. All required testing was completed, which included testing for: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Latex and USP Physiochemical testing. All testing was completed with acceptable results.

Performance Testing Summary:
Non-clinical comparative performance bench testing was successfully completed to demonstrate that the new adhesive primer, and new resin (coextruded with the tip of the proposed Jagwire) meets the Product Specifications of the currently marketed Jagwire Guidewires. This testing included: Tip Adhesion Shear Strength, End Product Tip Tensile, Tip Column Strength, Dimensional Test for Tip Outer Diameter, Tip Cantilever Strength, Atraumatic Tip, and Appearance and Cleanliness.

8. Conclusion:
Boston Scientific has demonstrated that the proposed Jagwire™ Guidewires are substantially equivalent to the currently marketed Jagwire™ Guidewires.