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

March 22, 2017

Boston Scientific Corporation
Mr. Keith Neligan
Senior Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, MN 55311

Re: K170636
Trade/Device Name: Fathom-16 Steerable Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: DQX
Dated: March 1, 2017
Received: March 2, 2017

Dear Mr. Neligan:

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)*
K170636

Device Name
Fathom™-16 Steerable Guidewire

Indications for Use *(Describe)*
The FATHOM -16 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

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.

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510(k) Summary

Per 21 CFR 807.92

Submitter's Name and Address

Boston Scientific Corporation
Three Scimed Place
Maple Grove, MN 55311
USA

Contract Information

Keith Neligan
Senior Regulatory Affairs Specialist
Phone 353 21 4531786
Fax: 353 21 4343354
Email: keith.neligan@bsci.com

Date Prepared 01 March 2017

Proprietary Name Fathom™ -16 Steerable Guidewire

Common Name Catheter Guidewire

Classification Class II per CFR 870.1330

Predicate Device(s) Boston Scientific Fathom™ -16 Steerable Guidewire:

- K111485, DQX, Jun 30, 2011

Device Description

Fathom™-16 Steerable Guidewires are hydrophilic coated, steerable guidewires intended to facilitate the placement of balloon dilatation catheters, and/or other therapeutic devices during peripheral vascular procedures. They are not intended for use in the cerebral or coronary vasculatures. The devices provided are non-pyrogenic, sterile, and intended for one procedure only.

The device shaft is coated with a thin hydrophilic coating over the distal section to provide lubricity, which aids in the navigation of distal, tortuous vasculature.

Accessories include a torque device, guidewire introducer and torque device. They are not intended to enter the body and have no patient contact.

Intended Use / Indications for Use

The Fathom™-16 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Comparison of Technological Characteristics

The Fathom™-16 Steerable Guidewires are similar in fundamental design, function, materials, packaging, sterilization, operating principle, intended use / indication for use and fundamental technology as the predicate device. Modifications were made to the guidewire length and tips (inclusion of angled tip) and associated packaging of the Fathom™-16 Steerable Guidewire.

Performance Data

The following testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. The Fathom™-16 Steerable Guidewires met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.

- Total Length
- Particulate
- Tip Shape Retention
- Torsional Strength
- Pre-Shape Tips

Conclusion

Boston Scientific has demonstrated that the modifications to the Fathom™-16 Steerable Guidewires are substantially equivalent in fundamental design, technology, function, materials, packaging, operating principle, and intended use / indication for use as the predicate device.