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

May 3, 2016

Boston Scientific Corporation
Yingying Gao
Sr. RA Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K160845
Trade/Device Name: Acquire Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODG, FCG
Dated: April 27, 2016
Received: April 28, 2016

Dear Yingying Gao,

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,

Herbert P. Lerner -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)*

K160845

Device Name
Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device

Indications for Use *(Describe)*
The Acquire™ Fine Needle Biopsy Device is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope.

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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SECTION 7.
510(K) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
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Marlborough, MA 01752

Contact: Yingying Gao
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Secondary Contact: Ashley Santos
Regulatory Affairs Manager
Telephone: 508-683-4359
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Date Prepared: March 24, 2016

2. Proposed Device:

Trade Name: Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device
Classification Name: Endoscopic Ultrasound System, gastroenterology-urology
Regulation Number: 876.1500 & 876.1075
Product Code: ODG and FCG
Classification: Class II

3. Predicate Device:

Trade Name: Expect™ Slimline Endoscopic Ultrasound Aspiration Needle
Manufacturer and Clearance Number: Boston Scientific Corp, K133312
Classification Name: Endoscopic ultrasound system, gastroenterology-urology
Regulation Number: 876.1500 & 876.1075
Product Code: ODG and FCG
Classification: Class II

4. Device Description:

Device Name: Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device

The Acquire™ device is comprised of the following:

- One (1) Acquire™ needle
- One (1) Syringe
- One (1) Stopcock

The Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device is a sterile single-use device. It is an endoscopic ultrasound aspiration needle that can be coupled to the biopsy channel of a Curvilinear Array (CLA) Echoendoscope with a standard luer connection and delivered into the digestive tract. The needle is used to acquire aspiration samples from lesions within and adjacent to the digestive system's major lumens that can be identified and targeted using the echoendoscope. An aspiration sample is obtained by penetrating the lesion with the needle while applying suction.

Syringe and stopcock are accessories to provide and control the vacuum suction to aspirate the sample.

5. Intended use/ Indications for Use:

The Acquire™ Fine Needle Biopsy Device is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope.

6. Technological Characteristics:

The proposed Acquire™ device is used to acquire samples in the digestive tract by coupling it with an ultrasound curvilinear endoscope. The proposed Acquire™ device is identical to the predicate Expect™ Slimline device, with the exception of the needle tip geometry. The proposed Acquire™ device will be offered with a Franseen needle tip (three-pronged tip). The proposed Acquire™ device shares the same technical characteristics as its predicate, the currently cleared Expect™ Slimline EUS-FNA needle (K133312).

7. Performance Data:

No performance testing is required to evaluate the new needle tip design. Verification activity has been performed on the proposed Acquire™ device, which demonstrates that the modified needle tip design met the pre-defined product specification: "Franseen" Needle Grind Specification.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Acquire™ Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device is substantially equivalent to the currently cleared Expect™ Slimline EUS-FNA needle (K133312).