October 27, 2017

Boston Scientific
Jennifer Edouard
Regulatory Specialist, Regulatory Affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K173184
Trade/Device Name: Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODG, FCG
Dated: September 28, 2017
Received: September 29, 2017

Dear Jennifer Edouard:

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 (DICE) 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 (DICE) 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,

Benjamin R. Fisher -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
Unknown K173184

Device Name
Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle

Indications for Use *(Describe)*
The Expect™ Slimline (SL) Needle is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope. It can also be used for delivery of injectable materials (fluids) or fiducials into tissue or for passage of accessory devices.

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.

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REVISED - SECTION 6 - 510(k) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Jennifer Edouard
Regulatory Affairs Specialist
Telephone: 508-683-6134
Fax: 508-683-5939

Date Prepared: September 28, 2017

2. Proposed Device:

Trade Name: Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle
Classification Name: Endoscope and Accessories
Regulation Number: 876.1500
Product Code: ODG & FCG
Classification: Class II

3. Predicate Device:

Trade Name: Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle
510(k) Number: K163058
Classification Name: Endoscopic Ultrasound System, Gastroenetrology-Urology and Biopsy Needle
Regulation Number: 876.1500 & 876.1075
Product Code: ODG & FCG
Classification: Class II

4. Proposed Device Description:

The Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle is and 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 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. Per manufacturer's instructions, the Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle can also be used for delivery of injectable materials (fluids) or fiducials into tissue or for passage of accessory devices.

5. Indications for Use:

The Expect™ Slimline (SL) Needle is designed to sample targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope. It can also be used for delivery of injectable materials (fluids) or fiducials into tissue or for passage of accessory devices.

6. Technological Characteristics:

There are no differences in the technological characteristics between the proposed device and the predicate Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle (K163058). The physical device will remain unchanged from the predicate K163058. The only change is to the allowable fiducial marker size that is compatible with the Expect Slimline 22ga Needle. The allowed fiducial size has increased from a 0.35mm OD to a 0.46mm OD. The original design specifications remain unchanged; however, additional performance testing was conducted to evaluate the ability of the device design to support the proposed change.

7. Performance Data:

Bench testing has been performed on the proposed Expect™ Slimline (SL) device. Bench Testing includes simulated use testing.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Expect™ Slimline (SL) is substantially equivalent to the Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle (K163058).