



Food and Drug Administration  
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January 30, 2017

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

Re: K163058  
Trade/Device Name: Expect™ Slimline (SL) Endoscopic Ultrasound  
Aspiration Needle  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: Class II  
Product Code: ODG, FCG  
Dated: October 31, 2016  
Received: November 1, 2016

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 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,

**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

## Indications for Use

510(k) Number (if known)

UNKNOWN - K163058

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.

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## **SECTION 5 - 510(k) SUMMARY**

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### **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: October 31, 2016

#### **2. Proposed Device:**

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

#### **3. Predicate Device:**

Trade Name: Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle  
510(k) Number: K133312  
Classification Name: Endoscopic Ultrasound System, Gastroenterology-Urology  
and Biopsy Needle  
Regulation Number: 876.1500 & 876.1075  
Product Code: ODG & FCG  
Classification: Class II

Trade Name: ECHO Tip Ultra High Definition Ultrasound Access Needle  
510(k) Number: K092359  
Classification Name: Biopsy Needle  
Regulation Number: 876.1075  
Product Code: FCG  
Classification: Class II

Trade Name: BNX Fine Needle Aspiration System  
510(k) Number: K150891  
Classification Name: Biopsy Needle and Marker, Radiographic, Implantable  
Regulation Number: 876.1075 & 878.4300  
Product Code: FCG & NEU  
Classification: Class II

#### **4. Proposed Device Description:**

The Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle 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 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 (K133312). The physical device will remain unchanged from the predicate K133312, but the expanded indications require changes to the product DFU. The original design specifications remain unchanged; however, additional performance criteria were introduced to evaluate the ability of the device design to support the proposed indications for use.

#### **7. Performance Data:**

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

- Simulated Use Test Method
- Fluid Injection Capability

#### **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 (K133312), the ECHO Tip Ultra High Definition Ultrasound Access Needle (K092359) and the BNX Fine Needle Aspiration System (K150891).