



Food and Drug Administration
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October 22, 2015

Boston Scientific Corporation
Yingying Gao
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K151895
Trade/Device Name: Expect Pulmonary Endobronchial Ultrasound Transbronchial
Aspiration Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: September 24, 2015
Received: September 25, 2015

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

Indications for Use

510(k) Number *(if known)*
To Be Determined - K151895

Device Name
Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle

Indications for Use *(Describe)*

The Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle is designed to be used with endobronchial ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of the submucosal and extramural lesions of the gastrointestinal tract. Do not use this instrument for any purpose other than its intended use.

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 6.
510(K) SUMMARY

510(k) SUMMARY

1. Submitter:

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Date Prepared: July 9, 2015

2. Device:

Trade Name:	Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle
Device Common Name:	Endobronchial Ultrasound Transbronchial Aspiration Needle/ EBUS-TBNA needle
Classification Name:	Gastroenterology-urology biopsy instrument
Regulation Number:	876.1075
Product Code:	FCG
Classification:	Class II

3. Predicate Device:

Primary Predicate device:

Trade Name:	Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration needle
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Device Common Name: Endoscopic Ultrasound Aspiration needle /
EUS-FNA needle
Manufacturer: Boston Scientific Corporation
Clearance Number: K133312
Classification Name: Endoscope and accessories
Regulation Number: 876.1500
Product Code: ODG and FCG
Classification: Class II

And

Secondary Predicate device:

Trade Name: Single Use Aspiration Needle NA-201SX-4022
Device Common Name: Endobronchial Ultrasound Transbronchial Aspiration
Needle/ EBUS-TBNA needle
Manufacturer: Olympus Medical Systems Corporation
Clearance Number: K050503
Classification Name: Gastroenterology-urology biopsy instrument
Regulation Number: 876.1075
Product Code: FCG
Classification: Class II

4. Device Description:

Device Name: Expect™ Pulmonary Endobronchial Ultrasound Transbronchial
Aspiration Needle

The Expect™ Pulmonary device is comprised of the following:

- Expect™ Pulmonary needle
- Expect™ Pulmonary adaptor
- Syringe
- Stopcock

The Expect™ Pulmonary needle is an Endobronchial Ultrasound guided Transbronchial Aspiration Needle used for fine needle aspiration (FNA) of submucosal and extramural lesions of the gastrointestinal tract. The device consists of a sheath covered needle which extends into the accessory channel of an endobronchial ultrasound (EBUS) endoscope and is locked into place. A handle on the proximal end of the device is used to actuate the needle in order gather samples. Both the sheath and needle length are adjustable while in the scope. A stylet is in place in order to provide protection to the inside of the sheath during device passage

through the scope. The stylet may also be used to expel the sample after the procedure.

Expect™ Pulmonary adaptor is an accessory to be attached and locked onto the biopsy port of the bronchoscope. It allows Expect™ Pulmonary needle to pass through it and to be secured in place with a luer connection.

Syringe and stopcock are accessories to provide and control the vacuum suction to aspirate the sample. They also can be used to expel the samples after the procedure.

5. Intended use and Indications for Use:

Intended use:

Expect™ Pulmonary device is intended to be used with ultrasound endoscope for fine needle aspiration of the submucosal and extramural lesions of the accessible organ systems.

Indications for Use:

The Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle is designed to be used with endobronchial ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of the submucosal and extramural lesions of the gastrointestinal tract. Do not use this instrument for any purpose other than its intended use.

6. Technological Characteristics:

The proposed Expect™ Pulmonary device is designed to acquire sample in the Esophagus by coupling with an ultrasound bronchoscope. It has the following technological characteristics:

- Adjustable sheath length and sheath locking mechanism
- Adjustable needle length and needle locking mechanism
- Needle sharpness
- Needle echogenicity in ultrasound image
- Stylet with kink resistance
- Smooth actuation
- Aspiration capability
- Passage of device through the scope to the target position
- Secure scope attachment

The Expect™ Pulmonary device shares similar design characteristics with its primary predicate device Expect™ Slimline device. Both of them have the adjustable lengths of sheath and needle with similar sheath and needle locking mechanism. These two devices have the same sharp echogenic needle and kink resistant stylet with the exact same materials and designs. The only differences are Expect™ Pulmonary device has a shorter sheath length and a shorter adjustable needle length. In additional, the same

sheath material is shared between these two devices. The Expect™ Pulmonary sheath has a smaller outer and inner diameter and a shorter length. Based on the similarity of the needle, sheath, and the stylet, Expect™ Slimline and Expect™ Pulmonary devices have a similar actuation mechanism. The same syringe and stopcock are also shared between these two devices. As a result, their aspiration capabilities are identical.

The proposed Expect™ Pulmonary device has an adaptor that is attached and locked onto the biopsy port of the bronchoscope. The Expect™ Pulmonary device can pass through the adaptor and be secured in place with a luer connection. This Adaptor is similar to the adaptor biopsy valve of the Vizishot device.

The proposed device has the same intended use and similar technical characteristics as the currently marketed Boston Scientific Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration needle (K133312) and the Olympus Single Use Aspiration Needle NA-201SX-4022 (K050503).

7. Performance Data:

Biocompatibility Testing Summary:

The proposed Boston Scientific Expect™ Pulmonary devices were evaluated biocompatibility in accordance with ISO 10993-1:2009 Evaluation and Testing. The following tests were performed with acceptable results on the patient contacting portions of the Expect™ Pulmonary device: Cytotoxicity, Sensitization, Irritation, and Systemic Toxicity.

Performance Testing Summary:

Non-clinical comparative performance bench testing was successfully completed to establish substantial equivalence between the proposed Expect™ Pulmonary devices and its primary predicate device Expect™ Slimline device. The following tests were conducted on the Expect™ Pulmonary devices:

1. Device Flexibility
2. Device Passability
3. Device Durability (Robustness)
4. Needle and Sheath Adjustment Locking Force
5. Handle actuation force (Needle extension)
6. Needle Sharpness
7. Stylet Removal Force
8. Handle Home Position
9. Needle Extension Length
10. Adjustable Working Length (Sheath Extension length)
11. Needle to Luer Tensile Strength
12. Sheath to Sheath Hub (Actuation Guide)
13. Tensile strength; Adaptor to scope tensile
14. Device Luer to Adaptor Luer to Scope Tensile
15. Adaptor Lock & Unlock Force
16. Adaptor Suction

17. Needle Extension Length Marking
18. Sheath Length Adjustment Markings
19. Handle Rotation
20. Smooth Actuation

8. Conclusion:

Boston Scientific has demonstrated that the proposed Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle is substantially equivalent to the currently marketed Boston Scientific Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration needle (K133312) and the Olympus Single Use Aspiration Needle NA-201SX-4022 (K050503).