DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 10, 2015

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

Re: K151315
Trade/Device Name: Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: October 1, 2015
Received: October 2, 2015

Dear Ms. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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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)*
K151315

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 tracheobronchial tree. Do no 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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510(k) SUMMARY

1. Submitter:

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Date Prepared: October 29, 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:	Bronchoscope (flexible or rigid) and accessories
Regulation Number:	874.4680
Product Code:	EOQ
Classification:	Class II

3. Predicate Device:

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

And

Reference device:

Trade Name:	Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration needle
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

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 device is an Endobronchial Ultrasound guided Transbronchial Aspiration Needle used for fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree. 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/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 tracheobronchial tree. 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 Airway 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

Comparison to Predicate:

The proposed Expect Pulmonary device is substantially equivalent to the current marketed predicate, the Olympus Single Use Aspiration Needle NA-201SX-4022 (K050503). The Expect Pulmonary device has similar technological characteristics as the predicate, that is, they operate in the same manner to obtain a tissue biopsy using an ultrasound endoscope. The indication for use of the proposed Expect Pulmonary device is nearly identical to the predicate device.

The comparison of the proposed Expect Pulmonary device and the Olympus Vizishot device is provided in the following Table 6-1.

Table 6-1 . Comparison of Key Characteristics

Device Characteristics	Predicate Olympus Vizishot device K050503	Proposed Device BSC Expect™ Pulmonary Device
Indications for Use	This instrument has been designed to be used with ultrasonic endoscopes for ultrasonically guided fine needle aspiration (FNA) of submucosal and extramural lesions of the tracheobronchial tree and the gastrointestinal tract. Do not use this instrument for any purpose other than its intended 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 tracheobronchial tree. Do not use this instrument for any purpose other than its intended use.
Single-Use	Single Use	Identical
Sterile	EO	Identical
Mechanism of Action for Needle Advancement	Manual	Identical
Mechanism for Tissue Sampling	Aspiration	Identical
Number of Device Passes during a procedure	Multiple Passes	Identical
Needle Gauge Size	21ga & 22ga	22ga & 25ga
Ability to Visualize with Endoscopic Ultrasound	Echogenic signature on distal end of device	Identical
Sheath Length	Adjustable	Identical.
Minimum Working Channel Compatibility	2.0mm (for both 22ga and 21ga)	Identical. 2.0mm (for both 22ga and 25ga)
Device to scope attachment	Adaptor biopsy valves Attachment for Olympus ultrasound bronchoscopes.	Adaptor Attachment compatible with Olympus and Fujinon ultrasound bronchoscopes.

The primary difference between the proposed Expect™ Pulmonary device and its predicate devices is the gauge size, patient contact materials and adjustable needle length. With the fully completed biocompatibility and performance bench testing, BSC considers these differences do not raise questions about the safety or effectiveness of the device. Based on the comparison above BSC considers the proposed Expect™ Pulmonary device substantially equivalent to the predicate devices.

The currently cleared Boston Scientific device Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration needle (K133312) is used as a reference device based on its design similarity to the Expect™ Pulmonary device.

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.

Sterilization Testing summary:
The proposed Boston Scientific Expect™ Pulmonary devices meet the requirements of ISO 11135-1:2007 "Sterilization of health care products – Ethylene oxide -- Part 1: Medical devices requirements for development, validation and routine control of a sterilization process for medical devices". This product's Ethylene oxide (EO) sterilization cycle is validated to achieve a minimum sterility assurance level (SAL) of 10^{-6}. And the product Ethylene oxide residual levels conform to ISO 10993-7:2008 (R: 2012) "Biological Evaluation of Medical Devices- Part 7: Ethylene Oxide Sterilization Residuals".

Performance Testing Summary:
Non-clinical performance testing was conducted on the Expect™ Pulmonary device which demonstrates the device met the required specifications. The proposed Boston Scientific Expect™ Pulmonary device and packaging were successfully verified after nominal and accelerated age tests, showing the Expect™ Pulmonary device met its shelf life requirements.

The following bench tests were performed:

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
21. Packaging

8. Conclusion:

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