JAN - 3 2014

SECTION 6.
510(K) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Yingying Gao:
Regulatory Affairs Specialist
Telephone: 508-683-4356
Fax: 508-683-5939

Secondary Contact: Ashley Santos
Regulatory Affairs Manager
Telephone: 508-683-4359
Fax: 508-683-5939

Date Prepared: October 25th, 2013

2. Proposed Device:

Trade Name: Expect™ Slimline (SL) Endoscopic Ultrasound Aspiration Needle
Classification Name: Endoscope and Accessories & Endoscopic Ultrasound System
Regulation Number: 876.1500 & 876.1075
Product Code: ODG and FCG
Classification: Class II

3. Predicate Device:

Trade Name: Expect™ Endoscopic Aspiration Needle
Manufacturer and Clearance Number: Boston Scientific Corp, K110030
Classification Name: Endoscope and Accessories & Endoscopic Ultrasound System
Regulation Number: 876.1500 & 876.1075
Product Code: ODG and FCG
Classification: Class II

And

Trade Name: Expect™ Endoscopic Aspiration Needle
Manufacturer and Clearance Number: Boston Scientific Corp, K112198
Classification Name: Endoscope and Accessories & Endoscopic Ultrasound System
Regulation Number: 876.1500 & 876.1075
Product Code: ODG and FCG
Classification: Class II

4. 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 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.

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.

6. Technological Characteristics:

The proposed Expect™ Slimline device is a new configuration, including slim handle design, low profile locking knobs with retention feature and modified handle internal components. The currently cleared Expect™ EUS-FNA needle is composed of an ergonomic handle with bigger outer diameter (K110030 & K112198).

7. Performance Data:

Bench Testing has been performed on the proposed Expect™ Slimline device, which demonstrates that the modified handle design met the required specifications for completed design verification tests. Bench Testing includes:

- Device Durability
- Needle and Sheath Adjustment Locking Force
- Handle (Needle) Actuation Force
- Device Handle Tensile Test
- Locking Knob Retention
- Smooth Actuation of Handle
- Needle Extension Length
- Device (Handle) Resistance to Torque

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Expect™ Slimline Endoscopic Aspiration Needle is substantially equivalent to the currently cleared Expect™ EUS-FNA devices (K110030 & K112198).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 3, 2014

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

Re: K133312
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: December 5, 2013
Received: December 6, 2013

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

SECTION 5.
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133312

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

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.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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