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SECTION 6
510(k) SUMMARY

MAR 30 2010

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-281-2163
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Contact: Ashley Pyle
Sr. Regulatory Affairs Specialist
Date Prepared: December 18, 2009

2. Device

Trade Name: Resound Endoscopic Ultrasound Aspiration Needle
Common Name: Kit, Needle, Biopsy
Classification Name: Gastroenterology-Urology Biopsy Instruments
Regulation Number: 876.1075
Product Code: FCG
Classification: Class II

3. Predicate Devices

Wilson-Cook EchoTip Ultrasound Needle (K934356)
Olympus Single-Use Aspiration Needle (K023272)

4. Device Description

The Resound Endoscopic Ultrasound Aspiration Needle (EUS-FNA) 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. Indication for Use:

The Resound EUS-FNA device is intended for sampling targeted submucosal and extramural gastrointestinal lesions through the accessory channel of a curvilinear echoendoscope.

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6. Technological Characteristics:

The proposed Resound EUS-FNA device has the same technological characteristics as the currently marketed Wilson-Cook EchoTip Ultrasound Needle and Olympus Aspiration Needle.

7. Performance Data:

Bench Testing has been performed on the finished Resound EUS-FNA device to demonstrate that the proposed device is substantially equivalent to the predicate devices.

8. Conclusion:

Boston Scientific has demonstrated that the proposed Resound EUS-FNA device is substantially equivalent to the currently marketed Wilson-Cook EchoTip Ultrasound Needle and the Olympus Aspiration Needle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Boston Scientific Corporation
% Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Inc.
2307 E. Aurora Road, Unit B7
TWINSBURG OH 44087

MAR 3 0 2010

Re: K100712
Trade/Device Name: Resound™ Endoscopic Ultrasound Aspiration Needle (EUS-FNA)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FCG and ODG
Dated: March 11, 2010
Received: March 12, 2010

Dear Mr. Lehtonen:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 5
INDICATIONS FOR USE
STATEMENT

Indications for Use:

510(k) Number (if known): ~~**To Be Determined**~~ K100712

Device Name: **Resound™ Endoscopic Ultrasound Aspiration Needle (EUS-FNA)**

Indications for Use:

The Resound EUS-FNA device 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 Part 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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K100712