MAY 16 2012 K121186

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Corrie Gooding
Regulatory Affairs Specialist
Telephone: 508-683-6643
Fax: 508-683-5939

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

Date Prepared: April 17, 2012

2. Proposed Device:

Trade Name: Radial Jaw™ 4 Pulmonary Biopsy Forceps
Classification Name: Bronchoscope (flexible or rigid) and accessories
Regulation Number: 874.4680
Product Code: BWH
Classification: Class II

3. Predicate Device:

Radial Jaw™ 4 Pulmonary Biopsy Forceps
Manufacturer and Clearance Number: Boston Scientific Corp, K102336
Classification Name: Bronchoscope (flexible or rigid) and accessories
Regulation Number: 874.4680
Product Code: BWH
Classification: Class II

4. Device Description:

The Radial Jaw™ 4 Pulmonary Biopsy Forceps (RJ4 Pulmonary) are sterile, single-use devices. The Radial Jaw™ 4 Pulmonary Biopsy Forceps are available in two jaw sizes: RJ4 Pulmonary Large Capacity is compatible with a 2.8mm or larger working channel endoscope and the RJ4 Pulmonary Standard Capacity is compatible with a 2.0mm or larger working channel endoscope. The RJ4 Pulmonary Large Capacity is only available without a needle. The RJ4 Pulmonary Standard Capacity is available with or without a needle. Both the RJ4 Pulmonary Large Capacity and Standard Capacity devices have a 100cm working length.

To operate the device, the user slides the spool back and forth over the handle body to open and close the jaws. The spool simultaneously actuates the dual pull wires, each of which run the length of the device and terminate with a connection to the jaw. The dual pull wire design allows

the jaws to pivot, thus enabling tissue acquisition with a tangential approach if desired. Using the RJ4 Pulmonary Biopsy Forceps the user can obtain a tissue sample by opening the jaws, pressing the jaws against the biopsy site, closing the jaws, and pulling the jaws away from the biopsy site.

5. Indications for Use:
These single-use biopsy forceps are specifically designed to collect tissue endoscopically for histologic evaluation. These forceps should not be used for any purpose other than their intended function.

6. Technological Characteristics:
The proposed Radial Jaw™ 4 Pulmonary Biopsy Forceps has a modified handle design as compared to the currently cleared Radial Jaw 4 Pulmonary Biopsy Forceps (K102336).

7. Performance Data:
Bench Testing has been performed on the proposed Radial Jaw™ 4 Pulmonary Biopsy Forceps to demonstrate that the modified handle design met the required specifications for the completed tests.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed Radial Jaw™ 4 Pulmonary Biopsy Forceps are substantially equivalent to the currently cleared Radial Jaw™ 4 Pulmonary Biopsy Forceps (K102336).

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
% Ms. Corrie Gooding
100 Boston Scientific Way
Marlborough, MA 01752

MAY 16 2012

Re: K121186
Trade/Device Name: Radial Jaw™ 4 Pulmonary Biopsy Forceps
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: BWH
Dated: April 17, 2012
Received: April 18, 2012

Dear Ms. Gooding:

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose, Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K121186

SECTION 5
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):	To Be Determined
Device Name:	Radial Jaw 4 Pulmonary Biopsy Forceps
Indications for Use:	The Radial Jaw 4 Pulmonary Biopsy Forceps are specifically designed to collect tissue endoscopically for histologic examination. These instruments should not be used for any purpose other than their intended use.

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)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

X

Prescription Use _____
(Per 21 CFR 801.109)

K121186