K102336

**SECTION 6**
**510(k) SUMMARY**

**1. Submitter**

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4359
Fax: 508-683-5939

Contact: Ashley Pyle
Sr. Regulatory Affairs Specialist
Date Prepared: January 5, 2011

JAN 2 4 2011

**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:**

Boston Scientific Radial Jaw™ Pulmonary Biopsy Forceps (K895415)
Boston Scientific Radial Jaw™ 3 Pulmonary Biopsy Forceps (K895415)

**4. Proposed Device Description:**
The Radial Jaw™ 4 Pulmonary Biopsy Forceps (RJ4 Pulmonary) are sterile, single-use (disposable) devices. The devices are packaged in a tyvek pouch, which is packaged into a carton box. 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. Intended Use/ 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 technological characteristics of the proposed Radial Jaw™ 4 Pulmonary Biopsy Forceps are similar to the predicate Radial Jaw™ Pulmonary Biopsy Forceps (K895415) and the Radial Jaw™ 3 Pulmonary Biopsy Forceps (K895415).

The proposed device has the same intended use and requires the same technique for obtaining biopsy samples as the predicate devices.

The RJ4 Pulmonary Standard Capacity Biopsy Forceps working length and endoscope working channel compatibility specifications are identical to the RJ3 Pulmonary Standard Capacity Biopsy Forceps. The RJ4 Pulmonary Large Capacity Biopsy Forceps working length and endoscope working channel compatibility specifications are identical to the RJ3 Pulmonary Large Capacity Biopsy Forceps.

The materials of the proposed RJ4 Pulmonary device are similar to the predicate RJ3 Pulmonary Biopsy Forceps.

**7. Performance Data:**
*In-vitro* testing has been performed on the finished Radial Jaw™ 4 Pulmonary Biopsy Forceps device and the proposed device met the required specifications for the completed tests.

The proposed RJ4 Pulmonary Biopsy Forceps were evaluated in accordance with EN ISO 10993-1: 2009. The following biocompatibility tests were performed on the biopsy forceps: Cytotoxicity, Sensitization, and Intracutaneous Reactivity.

The RJ4 Pulmonary Biopsy Forceps are E-Beam sterilized. The RJ4 Pulmonary Biopsy Forceps were adopted into the sterilization validation of the master product RJ4 Large Capacity. The sterilization validation was performed in accordance with EN ISO 11137-1:2006 and EN ISO 11137-2:2006. The validation method was VDmax25. The sterility assurance level is $10^{-6}$. The RJ4 Pulmonary Biopsy Forceps are not labeled as non-pyrogenic.

The following bench tests were conducted on the RJ4 Pulmonary Biopsy Forceps: Jaw Volume, Jaw Opening, Jaw Alignment and Engagement, Multi-Loop and Retroflex, Passability Force, Device Throw, Pivoting Head, Forceps Length for the Working Channel Portion of the Device, Forceps Operation after High Load, Forceps Integrity During Extreme Loading, Separation of Coil from Clevis, Separation of Sheath from Handle, Split Handle Design-Handle Separation, Split Handle Design- Spool Separation, Device Robustness, Endoscope Compatibility, Smooth Edges, and Distal End Protector.

**8. Conclusion:**

All biocompatibility tests conducted on the RJ4 Pulmonary Biopsy Forceps passed. Therefore, the RJ4 Pulmonary Biopsy Forceps are considered biocompatible for their intended use.

The RJ4 Pulmonary Biopsy Forceps met the requirements of the sterilization validation. Therefore, the RJ4 Pulmonary Biopsy Forceps are validated for E-Beam sterilization.

All device bench testing results were acceptable. The data demonstrate that the RJ4 Pulmonary Biopsy Forceps sufficiently met the design specifications and are suitable for the intended use.

Boston Scientific Corporation has demonstrated that the proposed Radial Jaw™ 4 Pulmonary Biopsy Forceps are substantially equivalent to Boston Scientific Corporation's currently marketed Radial Jaw™ Pulmonary Biopsy Forceps (K895415) and Radial Jaw™ 3 Pulmonary Biopsy Forceps (K895415).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Boston Scientific Corporation
c/o Ms. Ashley Pyle
Sr. Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

JAN 24 2011

Re: K102336
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: January 5, 2011
Received: January 6, 2011

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 and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**INDICATIONS FOR USE STATEMENT**

Indications for Use:

510(k) Number (if known): **To Be Determined** K102336

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__ (Part 21 CFR 801 Part D) AND/OR Over-The-Counter Use ____ (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)

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

510(k) Number K102336