K101657

SECTION 6
510(k) SUMMARY

1. Submitter

Boston Scientific Corporation
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OCT 5 2010

Contact: Ashley Pyle
Sr. Regulatory Affairs Specialist
Date Prepared: June 7, 2010

2. Proposed Device:

Trade Name: Radial Jaw™ 4 Hot Biopsy Forceps
Classification Name: Forceps, Biopsy, Electric
Regulation Number: 876.4300
Product Code: KGE
Classification: Class II

3. Predicate Device:

Boston Scientific Radial Jaw™ Hot Biopsy Forceps (K910964)
Boston Scientific Radial Jaw™ 3 Hot Biopsy Forceps (K910964)
Olympus Disposable Hot Biopsy Forceps (K955052)

4. Proposed Device Description:

The Radial Jaw™ 4 Hot Biopsy Forceps (RJ4 Hot) are sterile, single-use devices. The Radial Jaw™ 4 Hot Biopsy Forceps have a jaw size compatible with a 2.8mm or larger working channel endoscope and are available with a 240cm working length.

The RJ4 Hot device provides the user the ability to cauterize via an electrical current passed through the device from an electrosurgical generator. The generator is attached to the connector located in the spool. The connector contacts the dual pull wires, which provides an electrical path to the jaws of the device.

To open and close the jaws the user slides the spool back and forth over the handle body. Using the RJ4 Hot device the user can cauterize and remove polyps by opening the jaws, pressing the jaws against the tissue site, closing the jaws, applying an electrical current through the connector and pulling the jaws away from the tissue site.

5. Intended Use/ Indications for Use:

These Single-Use Hot Biopsy Forceps are intended to be used through an endoscope to cauterize and remove polyps and/or tissue specimens throughout the alimentary tract. The alimentary tract includes the esophagus, stomach, duodenum, jejunum, ileum and colon.

6. Technological Characteristics:

The proposed Radial Jaw™ 4 Hot Biopsy Forceps are nearly identical in design, materials, and manufacturing processes to the predicate Radial Jaw™ Hot Biopsy Forceps (K910964), Radial Jaw™ 3 Hot Biopsy Forceps (K910964) and the Olympus Disposable Hot biopsy Forceps (K955052).

7. Performance Data:

Bench testing and Electrical Safety Testing have been performed on the finished Radial Jaw™ 4 Hot Biopsy Forceps device per the direction of the *Guidance for the Content of Premarket Notifications for Biopsy Devices Used in Gastroenterology and Urology*. Bench testing and Electrical Safety Testing demonstrated that the proposed device is substantially equivalent to the predicate devices.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Radial Jaw™ 4 Hot Biopsy Forceps are substantially equivalent to Boston Scientific Corporation's currently marketed Radial Jaw™ Hot Biopsy Forceps (K910964), Radial Jaw 3 Hot Biopsy Forceps (K910964) the Olympus Disposable Hot Biopsy Forceps (K955052).

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

Ms. Ashley Pyle
Sr. Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
MARLBOROUGH MA 01752

OCT 5 2010

Re: K101657
Trade/Device Name: Radial Jaw 4 Hot Biopsy Forceps
Models: M00515031, M00515032 and M00515033
Regulation Number: 21 CFR §876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: II
Product Code: KGE
Dated: September 6, 2010
Received: September 8, 2010

Dear Ms. Pyle:

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,

Herbert P. Lerner, M.D., Director (Acting)
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

Indications for Use:

510(k) Number (if known): ~~To Be Determined~~ K101657

Device Name: **Radial Jaw 4 Hot Biopsy Forceps**

Indications for Use:

These Single-Use Biopsy Forceps are intended to be used through an endoscope to cauterize polyps and/or tissue specimens throughout the alimentary tract. The alimentary tract include the esophagus, stomach, duodenum, jejunum, ileum, and colon.

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, Gastro-Renal, and Urological Devices
510(k) Number K101657