K102764
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SECTION 6
510(k) SUMMARY

DEC 2 2 2010

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4347
Fax: 508-683-5939

Contact: Elena Nieves
Sr. Regulatory Affairs Specialist
Date Prepared: August 30, 2010

2. Device

Trade Name: Resolution II Clip
Common Name: Endoscopic Clipping Device
Classification Name: Hemorrhoidal Ligator
Regulation Number: 876.4400
Product Code: FHN and MND
Classification: Class II

3. Predicate Devices

Boston Scientific Corporation, Resolution Hemostasis Clipping Device (K040148)

4. Device Description

The Resolution II Clip consists of a pre-loaded, radiopaque, single-use clip on a flexible delivery system.

The Resolution II Clip is designed to be compatible with Gastroscopes with working channels ≥2.8, and/or Duodenoscopes and Colonoscopes with working channels ≥3.2mm.

The Resolution II Clip jaws are engineered to open and close no more than five times, aiding in repositioning of the clip at the lesion site. Opening and closing capability may be limited by clinical circumstances and patient anatomy, among other factors.

The Resolution II Clip will be offered in 155cm and 235cm lengths. The deployed clip is constructed of stainless steel while the delivery system is constructed of stainless steel, polyethylene, and polyester materials.

5. Indication for Use:

The Resolution II Clip is indicated for clip placement within the Gastrointestinal Tract for the purpose of:

1. Endoscopic Marking
2. Hemostasis for:
   - Mucosal/sub-mucosal defects < 3 cm
   - Bleeding ulcers
   - Arteries <2 mm
   - Polyps < 1.5 cm in diameter
   - Diverticula in the colon
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel
4. As a supplementary method for closure of GI tract luminal perforations <20mm that can be treated conservatively

6. Technological Characteristics:

The proposed Resolution™ II Clip has the same technological characteristics as the predicate Resolution™ Hemostasis Clipping Device (K040148).

The proposed device has the same intended use and is placed using the same methodology as the predicate device via a flexible delivery system. However, the proposed device functions in a different manner by allowing for clip placement within the gastrointestinal tract with fewer deployment steps.

The materials of the proposed Resolution II Clip can be found above in part 4 of this 510(k) summary.

7. Performance Data:

The proposed Resolution II Clip deployed clip was evaluated in accordance with EN ISO 10993-1:2009. The following tests were performed on the deployed clip: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Subacute (Subchronic) Toxicity –Intraperitoneal and Intravenous, Genotoxicity - Ames Assay and Mouse Lymphoma, Implantation, and USP Physicochemical.

The delivery system was evaluated in accordance with EN ISO 10993-1:2009. The following tests were performed on the delivery system: Cytotoxicity, Sensitization, and Intracutaneous Reactivity.

The proposed Resolution II Clip was evaluated in accordance with ISO 14630:2008. The following tests were conducted on the Resolution II Clip: Forces, Tensile Strengths, Corrosion Resistance, Dimensional, and Endoscope Compatibility.

8. Conclusion:

All biocompatibility tests conducted on the Resolution II Clip passed. Therefore, the Resolution II Clip is considered biocompatible for its intended use.

All device bench test results were acceptable. The data demonstrate that the Resolution II Clip sufficiently meets the design specifications and is suitable for the intended use.

Boston Scientific has demonstrated that the proposed Resolution II Clip is substantially equivalent to Boston Scientific Corporations currently marketed Resolution Clip (K040148).

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

March 25, 2015

Boston Scientific Corporation
Elena Nieves
Sr. Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K102764
Trade/Device Name: Resolution II Clip
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated (Date on orig SE ltr): September 23, 2010
Received (Date on orig SE ltr): September 24, 2010

Dear Elena Nieves,

This letter corrects our substantially equivalent letter of December 22, 2010.

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,

Joyce M. Whang -S

for 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

Indications for Use:

510(k) Number (if known): ~~To Be Determined~~ K102764

DEC 2 2 2010

Device Name: **Resolution II Clip**

Indications for Use:

The Resolution II Clip is indicated for clip placement within the Gastrointestinal Tract for the purpose of:

1. Endoscopic Marking
2. Hemostasis for:
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   - Arteries < 2 mm
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   - Diverticula in the colon
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4. As a supplementary method for closure of GI tract luminal perforations <20mm that can be treated conservatively

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 K102764