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SECTION 5
510(k) SUMMARY

DEC 03 2012

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752
Telephone: 508-683-4454
Fax: 508-683-5939

Contact: Thomas Hirte
Senior Manager Regulatory Affairs
Date Prepared: August 30, 2012

2. Device

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

3. Predicate Devices

The Boston Scientific Corporation, Resolution™ Hemostasis Clipping Device (K040148).

4. Device Description

The Resolution™ Hemostasis Clipping Device is a sterile, single-use, endoscopic clipping device consisting of two main components; the delivery system, and the clip.

The delivery system is made up of a handle and delivery catheter. The delivery system is constructed using thermoplastic elastomers, stainless steel, polyethylene, and polyester materials. The Resolution™ Hemostasis Clipping Device delivery system is offered in 155cm and 235cm working lengths.

The clip consists of a stainless steel capsule, and clip arms, a Cobalt Chrome Yoke, and a styrene tension breaker. The clip is deployed from the delivery system during use. The Resolution clip jaws are engineered such that they can be opened and closed up to 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.

5. Indication for Use:

The Resolution™ Hemostasis Clipping Device is indicated for endoscopic clip placement within the gastrointestinal tract for the purpose of:

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

6. Technological Characteristics:

There are no differences in the technological characteristics between the proposed and predicate devices. The purpose of this Traditional 510(k) is to request a labeling claim that the proposed Resolution™ Hemostasis Clipping Device clips are Magnetic Resonance (MR) Conditional and may be used for both 1.5 and 3.0 Tesla Magnetic Resonance Imaging (MRI) devices.

7. Performance Data:

Non-clinical bench testing was conducted to support the MR Conditional labeling claim.

8. Conclusion:

Boston Scientific has demonstrated that the proposed Resolution™ Hemostasis Clipping Device is substantially equivalent to currently marketed Resolution™ Hemostasis Clipping Device (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
Thomas Hirte
Senior Manager, Regulatory Affairs
100 Boston Scientific Way
Marlborough, MA 01752

Re: K122660
Trade/Device Name: Resolution™ Hemostasis Clipping Device
Regulation Number: 21 CFR§ 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated (Date on orig SE ltr): November 26, 2012
Received (Date on orig SE ltr): November 27, 2012

Dear Thomas Hirte,

This letter corrects our substantially equivalent letter of December 14, 2012.

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

K122660

SECTION 4
INDICATIONS FOR USE
STATEMENT

510(k) Number (if known): K122660 ~~To Be Determined~~

Device Name: Resolution™ Hemostasis Clipping Device

Indications for Use: The Resolution™ Hemostasis Clipping Device is indicated for use endoscopic clip placement within the gastrointestinal tract for the purpose of:

1. Endoscopic Marking
2. Hemostasis for;
   - Mucosal/sub-mucosal defects < 3cm
   - Bleeding ulcers
   - Arteries < 2cm
   - Polyps <1.5cm in diameter
   - Diverticula in the colon
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel
4. As a supplemental closure method of 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)

Herbert P. Lerner

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K122660