SECTION 5
510(k) SUMMARY

510(k) SUMMARY

1. SUBMITTER:

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

Contact: Elena Nieves
Principal, Regulatory Affairs Specialist
Date Prepared: November 24, 2014

2. DEVICE:

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

3. PREDICATE DEVICE:

Name of Device:	Resolution™ Hemostasis Clipping Device
510(k) Number:	K122660
Classification Name:	Hemorrhoidal Ligator
Regulation Number:	876.4400
Product Code:	FHN and MND
Classification:	Class II

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.

There are no associated accessories included with this device.

5. INDICATIONS FOR USE:

The Resolution™ Hemostasis Clipping Device is indicated for clip placement within the gastrointestinal (GI) 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
    - Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection
3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel; and Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus
4. As a supplemental closure method of luminal perforations < 20 mm that can be treated conservatively

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

There are no differences in the technological characteristics between the proposed device and the predicate Resolution Hemostasis Clipping Device (K122660). The purpose of this Traditional 510(k) is to request an expanded indication for the proposed Resolution™ Hemostasis Clipping Device. The physical device will remain unchanged from the predicate K122660, but the expanded indication requires a change to the product labeling. All other design specifications remain unchanged.

7. PERFORMANCE DATA:

Non-Clinical Testing:
No performance data was required for this submission. The proposed device meets the requirements of ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing", ISO 11135-1 "Sterilization of Health Care products - Ethylene Oxide - Part 1: Requirements for Development, Validation, and Routine Control of Sterilization processes for Medical Devices", and ISO 10993-7 "Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals", as the design and materials remain unchanged from that of the predict Resolution Hemostasis Clipping Device (K122660).

Clinical Data:
Boston Scientific used published clinical results on the Resolution Hemostasis Clipping Devices used for clipping fully covered esophageal self-expanding metal stents; and delayed bleeding rates with prophylactic clipping.

Vanbiervliet G, Filippi J, Karimdjee BS, et al, "*The role of clips in preventing migration of fully covered metallic esophageal stents: a pilot comparative study*", Surg Endosc, 2012. 26: p. 53-59, prospectively compared SEMSs that were anchored (affixed) to the wall of the esophagus with the Resolution Clip device to non-clipped SEMSs. Statistical analysis via Fisher Exact test indicated that stent migration was significantly (p=0.003) less when Resolution Clips were used to anchor stents in place (13%) as compared to stents that were not anchored with clips (57%). Furthermore, there were no complications observed in either group.

The report by Liaquat, H, Rohn E, Rex DK, Gastrointest Endosc, 2013. 77(3): p. 401-407, entitled "*Prophylactic clip closure reduces risk of delayed postpolypectomy hemorrhage: experience in 277 clipped large sessile or flat colorectal lesions and 247 control lesions*", compared rates of delayed bleeding for non-clipped versus prophylactically clipped defects post-polypectomy. The clipped lesions were treated with the Resolution Clip and had a mean size of 31 mm (range 20-100 mm).

A multivariate analysis indicated that the lesions that were not clipped were 6 times more likely to have a delayed bleed (95% CI, 2.0-18.5; p=0.002) than a fully clipped lesion. Furthermore, lesions that were partially clipped were not significantly (p=0.17) more likely to have delayed bleeding compared with fully clipped lesion. A Fisher Exact test comparing prophylactically clipped, complete and partial, to non-clipped defects indicated that the rate of delayed bleeding in the Resolution Clip group, 2.5%, was statistically less than that of the non-clip group 9.7% (p=0.006).

The results indicate that prophylactic polypectomy site closure with Resolution Clips is associated with a reduced the risk of delayed post polypectomy hemorrhage. These results strongly support the safety and effectiveness of the prophylactic use of the Resolution Clip in reducing the risk of delayed bleeding.

The clinical results demonstrate that the Resolution Hemostasis Clipping Device can be safely and effectively used within the gastrointestinal (GI) tract for the purpose of hemostasis for prophylactic clipping to reduce the risk of delayed bleeding post lesion resection; and anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus.

8. CONCLUSION:

Boston Scientific Corporation has demonstrated that the proposed Hemostasis™ Clipping Device can be safely and effectively used for its proposed expanded indication.

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
Principal, Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K142973
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): October 15, 2014
Received (Date on orig SE ltr): October 16, 2014

Dear Elena Nieves,

This letter corrects our substantially equivalent letter of December 1, 2014.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142973

Device Name
Resolution™ Hemostasis Clipping Device

Indications for Use *(Describe)*
The Resolution Hemostasis Clipping Device is indicated for clip placement within the gastrointestinal (GI) 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
- Prophylactic clipping to reduce the risk of delayed bleeding post lesion resection

3. Anchoring to affix jejunal feeding tubes to the wall of the small bowel; and Anchoring to affix fully covered esophageal self-expanding metal stents to the wall of the esophagus
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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