DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 6, 2015

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

Re: K151802
Trade/Device Name: Resolution 360 Clip
Regulation Number: 21 CFR §876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: II
Product Code: PKL
Dated: June 30, 2015
Received: July 2, 2015

Dear Elena Nieves,

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 -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)*
K151802

Device Name
Resolution 360 Clip

Indications for Use *(Describe)*
The Resolution 360 Clip is indicated for placement in the Gastrointestinal tract for:
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

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5
510(K) SUMMARY

510(k) SUMMARY

1. Submitter:
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Elena Nieves
Principal Regulatory Affairs Specialist
Tel: 508-683-4347
Fax: 508-683-5939
Date Prepared: August 3, 2015

2. Proposed Device:
Trade Name: Resolution 360™ Clip
Device Common Name: Hemostatic Metal Clip for the GI Tract
Classification Name: Hemorrhoidal Ligator
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II

3. Predicate Device:
Trade Name: Resolution™ Hemostasis Clipping Device
Device Common Name: Hemostatic Metal Clip for the GI Tract
Classification Name: Hemorrhoidal Ligator
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II
510(k) Clearance Number: K142973

4. Device Description:

The Resolution 360™ Clip is a sterile device consisting of a pre-loaded, radiopaque, single-use, endoscopic clipping device consisting of two main components: the delivery system and the clip.

The delivery system consists of a handle and delivery catheter. The delivery system is constructed using stainless steel, and polyester materials. The delivery system will allow for the device to rotate at the distal end. The Resolution 360™ Clip 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™ 360 Clip jaws are engineered such that they can be opened and closed up to five times prior to deployment, aiding in repositioning of the clip at the lesion site. Re-opening, closing, and rotation capability may be limited by clinical circumstances and patient anatomy. There are no associated accessories included with this device.

5. Indications for Use:
The Resolution 360 Clip 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. Technological Characteristics:
The proposed Resolution™ 360 Clip has similar technological characteristic as the predict Resolution™ Hemostasis Clipping Device (K142973).

The proposed device has the identical intended use and is placed using the identical methodology as the predicate device. However, the proposed device functions in a different manner by allowing for the user to rotate the clip jaws 360° via a control knob prior to deployment.

The materials of the proposed Resolution 360 Clip are identical to the predicate device.

7. Performance Data:
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”,

The following bench tests were performed on the Resolution™ 360 Clip: Clip Assembly Repeated Open/Close; Retention Force; Clip Approach; Torque; Rotation; Clip Opening and Close Force; Clip Deployment; Force; Scope Compatibility/Usability; Working Length; Endoscope Damage; Biopsy Valve Compatibility; Coil to Handle tensile; and Push/Pull wire to Handle Spool Slider tensile.

The testing performed demonstrated that the proposed and predicate delivery systems are equivalent.

8. Conclusion:
Boston Scientific Corporation has demonstrated that the proposed Resolution 360 Clip is substantially equivalent to the currently cleared Resolution Hemostatis Clipping Device (K142973).