September 1, 2020

Boston Scientific Corporation
Elena Hennessey
Fellow, Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K193424
Trade/Device Name: Resolution 360™ ULTRA Clip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: II
Product Code: PKL
Dated: July 31, 2020
Received: August 3, 2020

Dear Elena Hennessey:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193424

Device Name
Resolution 360 ULTRA Clip

Indications for Use *(Describe)*
The Resolution 360 ULTRA 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 <3cm
-Bleeding ulcers
-Arteries <2mm
-Polyps <1.5cm 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)*

[X] 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 Hennessey
Fellow Regulatory Affairs Specialist
Tel: 508-683-4347
Date Prepared: December 9, 2019

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

3. Predicate Device:

Primary Predicate Device:
Trade Name: Resolution 360™ Clip
Common Name: Hemostatic Metal Clip for the GI Tract
Regulation Name: Hemorrhoidal Ligator
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II
510(k) Clearance Number: K151802

And

Secondary Predicate Device:
Trade Name: SureClip MAX Repositionable Hemostasis Clip
Common Name: Hemostatic Metal Clip for the GI Tract
Regulation Name: Hemorrhoidal Ligator
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II
510(k) Clearance Number: K182556

And

Reference Device:
Trade Name: Resolution™ Hemostasis Clipping Device
Common Name: Hemostatic Metal Clip for the GI Tract
Regulation Name: Hemorrhoidal Ligator
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II
510(k) Clearance Number: K122660 and K142973

4. Device Description:

The Resolution 360™ ULTRA 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™ ULTRA Clip delivery system is offered in a 235cm working length.

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 ULTRA 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. The clip jaws will be available with a 17mm clip opening.

5. Indications for Use:
The Resolution 360 ULTRA 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 ULTRA Clip has different technological characteristic compared to the primary predict Resolution 360™ Clip (K151802). However, both the proposed and the proposed and primary predicate devices can pass through forward viewing endoscopes with a working channel equal to or greater than 2.8 mm to the target position. In addition, the materials of the components used to manufacture the deployed clip components of the proposed and primary predicate are identical.

The proposed Resolution 360 ULTRA Clip has identical indications for use as the primary predicate Resolution 360 Clip. The proposed device has the identical intended use and is placed using the identical methodology as the predicate devices. The proposed device will be available with a 17mm clip opening which is similar to the secondary predicate SureClip MAX Repositionable Hemostasis Clip (K182556) and functions in the same manner as the primary predicate Resolution 360 Clip (K151802). However, the proposed devices deployed clip length is slightly longer than that the predicate devices.

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

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 ULTRA Clip: Clip Assembly Repeated Open/Close; Clip Opening Gap; Retention Force; Clip Opening Force; Clip Close Force; Scope Compatibility/Usability; and Endoscope Damage – Clip Passibility.

In addition, the proposed device was evaluated for Magnetic Resonance to support MR Conditionality for the proposed device. Magnetic Resonance (MR) testing along with scientifically based rationale for clinically relevant acceptance criteria consistent with the recommendations contained in the FDA Guidance for Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment (issued December11, 2014) were completed. The results from the test data and scientific rationale have determined the Resolution 360™ ULTRA Clip to be an MR Conditional device.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Resolution 360 ULTRA Clip is substantially equivalent to the currently cleared Resolution 360 Clip (K151802) and SureClip MAX Repositionable Hemostasis Clip (K182556) as the performance of the proposed device meets the requirements of its pre-defined acceptance criteria and intended use.