September 14, 2022

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

Re: K222503
Trade/Device Name: Resolution Clip, Resolution 360 Clip, Resolution 360 ULTRA Clip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: August 16, 2022
Received: August 18, 2022

Dear Jia Huang:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222503

Device Name
Resolution™ Clip
Resolution 360™ Clip
Resolution 360™ ULTRA Clip

Indications for Use *(Describe)*
The proposed Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip are 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

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary for Resolution Clip, Resolution 360 Clip, Resolution 360 ULTRA Clip

1. Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Jia Huang
Principal Regulatory Affairs Specialist
Tel: 617-912-0826
Date Prepared: August 16, 2022

2. Proposed Device

Trade Name: Resolution™ Clip
Classification Name: Hemostatic Metal Clip for the GI Tract
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II

Trade Name: Resolution 360™ Clip
Classification Name: Hemostatic Metal Clip for the GI Tract
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II

Trade Name: Resolution 360™ ULTRA Clip
Classification Name: Hemostatic Metal Clip for the GI Tract
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II

3. Predicate Devices

Trade Name: Resolution™ Clip
Classification Name: Hemostatic Metal Clip for the GI Tract
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II
510(k) Clearance Number: K142973

Trade Name: Resolution 360™ Clip
Classification Name: Hemostatic Metal Clip for the GI Tract
Regulation Number: 876.4400

Product Code: PKL
Classification: Class II
510(k) Clearance Number: K151802

Trade Name: Resolution 360™ ULTRA Clip
Classification Name: Hemostatic Metal Clip for the GI Tract
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II
510(k) Clearance Number: K193424

4. Device Description

The Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip are sterile devices 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 assembly and delivery catheter. The delivery system of Resolution 360™ Clip and Resolution 360™ ULTRA Clip will allow for the device to rotate at the distal end. The clip delivery system is offered in a 155cm and 235cm working length for Resolution Clip and Resolution 360 Clip but only 235 cm for Resolution 360 ULTRA Clip. 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 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 (only for Resolution 360 Clip and Resolution 360 ULTRA Clip) may be limited by clinical circumstances and patient anatomy. There are no associated accessories included with this device. The Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip are designed to be compatible with endoscopes with working channels equal to or greater than 2.8 mm.

5. Indications for Use

The proposed Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip are 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

There is no change in intended use or design associated with this Special 510(k). The technological characteristics of the proposed Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip are identical to their respective predicate devices: Resolution™ Clip (K142973), Resolution 360™ Clip (K151802) and Resolution 360™ ULTRA Clip (K193424), with the exception of the MRI safety information in Instruction for Use and Product Information for Patients. In addition, minor modifications of the clinical information was also conducted in order to clarify information.

7. Substantial Equivalence

The proposed Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip do not have any change in material, design, specification, manufacturing technology, performance, biocompatibility or packaging to their respective predicate devices of Resolution™ Clip (K142973), Resolution 360™ Clip (K151802) and Resolution 360™ ULTRA Clip (K193424). The only change being introduced is to the MRI safety information in the Instruction for Use and Product Information for Patients. The changes to the MRI Safety information are based on the bench testing results of the predicate devices of Resolution™ Clip (K142973) and Resolution 360™ ULTRA Clip (K193424). The design requirements are not impacted by the labeling updates and the proposed devices are deemed substantially equivalent to the predicate devices and continues to meet the pre-defined device specification.

8. Performance Data

Performance testing (bench) was successfully completed to demonstrate compliance to the FDA MR Safety Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021. The testing included the following:

- Magnetically Induced Displacement Force
  ASTM F2052, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- Magnetically Induced Torque
  ASTM F2213, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- Heating by Radio Frequency (RF) Fields
  ASTM F2182, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- Image Artifact
  ASTM F2119, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

The testing was conducted using the predicate devices of Resolution™ Clip (K142973) and Resolution 360™ ULTRA Clip (K193424). The performance (bench) testing demonstrated

that the proposed Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip comply with the FDA MR Safety Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021, and are considered substantially equivalent to the predicate devices.

9. **Conclusion**

Boston Scientific Corporation has demonstrated that the proposed Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip with updated labeling including MRI safety information are compliant with the FDA MR Safety Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021, and substantially equivalent to the currently cleared predicate devices of Resolution™ Clip (K142973), Resolution 360™ Clip (K151802) and Resolution 360™ ULTRA Clip (K193424) as the performance of the proposed Resolution™ Clip, Resolution 360™ Clip and Resolution 360™ ULTRA Clip meets the requirement of the per-defined acceptance criteria and intended use.