February 6, 2025

Boston Scientific Corporation
Kyra McNamara
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 02472

Re: K250066
Trade/Device Name: Resolution Clip (M00522600); Resolution Clip (M00522601); Resolution Clip (M00522602); Resolution Clip (M00522610); Resolution Clip (M00522611); Resolution Clip (M00522612)
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal Ligator
Regulatory Class: Class II
Product Code: PKL
Dated: January 10, 2025
Received: January 10, 2025

Dear Kyra McNamara:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sivakami Venkatachalam -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250066

Device Name

Resolution Clip (M00522600);
Resolution Clip (M00522601);
Resolution Clip (M00522602);
Resolution Clip (M00522610);
Resolution Clip (M00522611);
Resolution Clip (M00522612)

Indications for Use *(Describe)*

The Resolution™ 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.

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.

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Kyra McNamara
Senior Regulatory Affairs Specialist
Telephone: (508)-382-0375
Date Prepared: January 10, 2025

2. Proposed Device:

Trade Name:	Resolution Clip (M00522600); Resolution Clip (M00522601); Resolution Clip (M00522602); Resolution Clip (M00522610); Resolution Clip (M00522611); Resolution Clip (M00522612)
Classification Name:	Hemostatic Metal Clip for the GI Tract
Regulation Number:	876.4400
Product Code:	PKL
Regulatory Class:	Class II

3. Predicate Device:

Trade Name:	Resolution™ Clip
Manufacturer:	Boston Scientific
510(k) Number:	K222503
Classification Name:	Hemostatic Metal Clip for the GI Tract
Regulation Number:	876.4400
Product Code:	PKL
Regulatory Class:	Class II

4. Device Description:

The Resolution™ 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 assembly and delivery catheter. The clip delivery system is offered in a 155cm and 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 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 and closing may be limited by clinical circumstances and patient anatomy, among other factors. The Resolution™ Clip is designed to be compatible with endoscopes with working channels equal to or greater than 2.8 mm.
There are no associated accessories included with this device.

5. Intended use/ Indications for Use:

The Resolution™ 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 purpose of this Special 510(k) is to remove the outer sheath component from the Resolution™ Clip device. Simulated Use testing confirmed that the device without the outer sheath continues to meet existing performance requirements. The Instructions for Use (IFU) will be updated to reflect the outer sheath removal. No further modifications are being made and the indications for use will remain unchanged from the predicate K222503.

7. Performance Data:

Non-clinical performance bench simulated use testing was completed to evaluate the design of the Resolution Clip device for the design modification to remove the outer sheath component.

Bench Testing included testing for the following design requirements:

- Device removal from the endoscope
- Device passability within the endoscope
- Absence of damage of the endoscope working channel

All testing was passing and demonstrates the device's ability to fulfill non-clinical performance bench testing requirements.

8. Conclusion:

Boston Scientific Corporation has demonstrated that the proposed Resolution™ Clip is substantially equivalent to the currently cleared Resolution™ Clip (K222503).