August 4, 2022

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

Re: K221124
Trade/Device Name: MANTIS Clip
Regulation Number: 21 CFR 876.4400
Regulation Name: Hemorrhoidal ligator
Regulatory Class: Class II
Product Code: PKL
Dated: July 1, 2022
Received: July 5, 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221124

Device Name
MANTIS™ Clip

Indications for Use *(Describe)*

The MANTIS 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.

SECTION 5: 510(K) SUMMARY

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: April 15, 2022

2. **Proposed Device**

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

3. **Predicate Device**

Primary Predicate Device:
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

Secondary Predicate Device:
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

Reference Device:
Trade Name: OTSC (Over-the scope-clip) System Set
Classification Name: Hemostatic Metal Clip for the GI Tract
Regulation Number: 876.4400
Product Code: PKL
Classification: Class II
510(k) Clearance Number: K101428

Reference Device:
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: K142987

4. Device Description

The MANTIS 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 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 MANTIS 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 MANTIS 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 jaw teeth are designed with smaller angle between the teeth and the clip arm body.

5. Indications for Use

The MANTIS 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 MANTIS Clip has different technological characteristics compared to the primary predicate Resolution 360 Clip (K151802) and the secondary predicate Resolution 360 ULTRA Clip (K193424). However, both the proposed and the primary predicate devices (K151802, K193524) can pass through forward viewing endoscope with a working channel equal to or greater than 2.8 mm to the target position. In addition, both the proposed and the primary predicate devices (K151802, K193524) have the same design to allow rotation of the clips. The materials of the components used to manufacture the deployed clip and the delivery catheter of the proposed and the primary and secondary predicate devices (K151802, K193424) are identical. The materials of the components used to manufacture the handle assembly of the proposed and the primary and secondary predicate devices (K151802, K193424) are identical except for the colorant of the handle with thumb ring which is non-patient contacting.

The proposed MANTIS Clip has identical indications for use as the primary predicate Resolution 360 Clip (K151802) and secondary predicate Resolution 360 ULTRA Clip (K193424). The proposed MANTIS Clip has identical intended use as the primary predicate Resolution 360 Clip (K151802) and secondary predicate Resolution 360 ULTRA Clip (K193424) and is placed using the identical methodology. The proposed MANTIS Clip has a jaw opening width between the primary predicate device (K151802) and the secondary predicate Resolution 360 ULTRA Clip (K193424). The proposed MANTIS Clip teeth length is longer than that of the primary and secondary predicate devices (K151802, 193424) but is shorter than the reference device OTSC System Set.

7. Substantial Equivalence

The proposed MANTIS Clip has identical design on the delivery system to primary predicate Resolution 360 Clip (K151802) and secondary predicate Resolution 360 ULTRA Clip (K193424).

The proposed MANTIS Clip has nearly identical design on the clip to its primary predicate Resolution 360 Clip (K151802) and secondary predicate Resolution 360 ULTRA Clip (K193424). The main difference between the proposed and predicate devices is the jaw teeth geometry. The proposed MANTIS Clip has longer and more curved jaw teeth design to allow capability to hold onto tissue after the clip is opened after being closed. All the materials for the clip's components are identical for the proposed MANTIS Clip and the primary predicate Resolution 360 Clip (K151802) and secondary predicate Resolution 360 ULTRA Clip (K193424).

Overall, the design requirements are not impacted by these minor design difference, the proposed device is deemed substantially equivalent to the predicate devices and continues to meet the pre-defined device specification.

8. Performance Data

The proposed MANTIS Clip meets the requirements of *ISO 10993-1 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 Routing Control of Sterilization Process for Medical Devices*, and *ISO 10993-7 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals*.

The product specifications of the proposed MANTIS Clip are nearly identical to its predicate, the primary predicate device (K151802) and the secondary predicate Resolution 360 ULTRA Clip (K193424). The following bench testing was conducted to evaluate the changes on the proposed device. All Performance testing (bench) was successfully completed.

Component	Product Specification	Result (Pass/Fail)
Clip	4.1 Clip Assembly Repeated Open/ Close Function	PASS
Clip	4.2 Clip Opening Gap	PASS
Clip	4.4 Deployed Clip: Retention Force	PASS
Clip	4.5 Clip Approach: Cantilever Force	PASS
Clip	4.6 Clip Approach: Vertical Oblique	PASS
Clip + Delivery System	4.7 Torque – Full Device	PASS
Clip	4.9.1 Clip Opening Force	PASS
Clip	4.9.2 Clip Close Force	PASS
Clip	4.14 Jaw Deflection	PASS
Clip	4.15 Grasping Capability	PASS
Clip + Delivery System	7.1 Scope Compatibility / Usability	PASS
Clip + Delivery System	7.3 Endoscope Damage – Clip Passability	PASS
Clip + Delivery System	7.6 Biopsy Valve Compatibility	PASS

In addition, the proposed MANTIS Clip was evaluated for Magnetic Resonance (MR) to support MR Conditionality. MR testing along with scientifically based rationale for clinically relevant acceptance criteria consistent with the recommendations contained in the *FDA Guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* were completed. The results from the test data and scientific rationale have determined that the proposed MANTIS Clip to be an MR Conditional device.

The results of above performance (bench) testing demonstrate that the proposed MANTIS Clip is considered substantially equivalent to the predicate devices.

9. Conclusion

Boston Scientific Corporation has demonstrated that the proposed MANTIS Clip is substantially equivalent to the currently cleared primary predicate Resolution 360 Clip (K151802) and secondary predicate device Resolution 360 ULTRA Clip (K193424) as the performance of the proposed MANTIS Clip meets the requirement of the per-defined acceptance criteria and intended use.