April 4, 2024

Boston Scientific Corporation
Alexis Erazo
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K233837
Trade/Device Name: Agile Esophageal Stent System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: March 4, 2024
Received: March 5, 2024

Dear Alexis Erazo:

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.

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,

Shanil P. Haugen -S

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)*
K233837

Device Name
Agile Esophageal Stent System

Indications for Use *(Describe)*
The Agile Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.

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) #: K233837

510(k) Summary

Prepared on: 2024-03-05

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Boston Scientific Corporation
Applicant Address	100 Boston Scientific Way Marlborough MA 01752 United States
Applicant Contact Telephone	508.382.0365
Applicant Contact	Ms. Alexis Erazo
Applicant Contact Email	alexis.erazo@bsci.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Agile Esophageal Stent System
Common Name	Esophageal prosthesis
Classification Name	Prosthesis, Esophageal
Regulation Number	878.3610
Product Code	ESW

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180144	Agile Esophageal Stent System	ESW
K211960	Agile Esophageal OTW Stent System	ESW

Device Description Summary

21 CFR 807.92(a)(4)

The Agile Esophageal Stent System consists of a self-expanding esophageal metal stent and a delivery system. The Agile Esophageal Stent is available partially or fully covered with silicone covering and in three diameter sizes: 14mm, 18mm and 23mm. The 14mm and 18mm diameter stents are pre-loaded on a 10.5Fr delivery system and the 23mm diameter stent is pre-loaded on an 18.5Fr delivery system. The 10.5Fr delivery system has a single central lumen to accommodate a 0.035" (0.89 mm) guidewire. The 18.5Fr delivery system has a single central lumen to accommodate a 0.038" (0.97mm) guidewire.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Agile Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the proposed Agile™ Esophageal Stent System device are identical to the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The proposed Agile™ Esophageal Stent System device is identical to the predicate device in design, material, chemical composition, fundamental technology, principle of operation, sterilization, packaging, shelf-life and manufacturing process.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Boston Scientific Corporation has demonstrated that the proposed Agile™ Esophageal Stent System are substantially equivalent to the previously cleared and currently marketed predicate Agile™ Esophageal Stent System (K180144 and K211960).

The proposed Agile Esophageal Stent System are identical to the predicate Agile Esophageal Stent System (K180144 and K211960) in intended use, indications for use, classification, principles of operation, technical characteristics, performance, and materials. The labeling changes do not raise different questions of safety and effectiveness. The testing performed on the proposed Agile™ Esophageal Stent System demonstrates the devices are substantially equivalent.

The substantial equivalence of the subject device was determined as per the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]."