November 22, 2021

Boston Scientific Corporation
Inderdeep Tiwana
Sr. Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K211960
Trade/Device Name: Agile Esophageal OTW Stent System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: October 19, 2021
Received: October 20, 2021

Dear Inderdeep Tiwana:

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 Haugen
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)*
K211960

Device Name
Agile Esophageal OTW Stent System

Indications for Use *(Describe)*
The Agile Esophageal Partially Covered and Fully Covered OTW 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)*

[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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510(k) Summary for Agile Esophageal OTW Stent System

1. Submitter

Boston Scientific Corporation
Endoscopy Division
100 Boston Scientific Way
Marlborough, MA 01752

Contact:

Primary Contact: Inderdeep Tiwana
Sr. Regulatory Specialist
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Director, Regulatory Affairs-Endoscopy
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Date Prepared: June 23, 2021

2. Device

Trade Name:	Agile Esophageal OTW Stent System
Classification Name:	Prosthesis, Esophageal
Product Code:	ESW
Device Class and Panel:	Class II
Classification Regulation:	21 CFR 878.3610

3. Predicate Devices

Stent

Trade Name:	Agile Esophageal Stent System
Manufacturer:	Boston Scientific Corp.
510(k) Clearance Number:	K180144
Classification Name:	Prosthesis, Esophageal
Product Code:	ESW
Device Class and Panel:	Class II
Classification Regulation:	21 CFR 878.3610

Delivery System:

Trade Name:	Wallflex Esophageal Fully & Partially Covered Stent System
Manufacturer:	Boston Scientific Corp.
510(k) Clearance Number:	K091510/ K073266
Classification Name:	Prosthesis, Esophageal
Product Code:	ESW
Device Class and Panel:	Class II
Classification Regulation:	21 CFR 878.3610

4. Device Description

The Agile Esophageal 23mm Partially Covered and Fully Covered Over the Wire (OTW) Stent System is comprised of a metallic implantable stent pre-loaded inside of a flexible delivery system. The stent is made from braided Nitinol wires which form a self-expanding, radiopaque (RO) cylindrical mesh. The stent has flares at each end to aid in minimizing migration after the stent is placed in the esophagus. The flares are a wider diameter than the stent body. The wire ends are looped at the end of the stent. The proximal and distal stent ends each have a continuous suture threaded around their circumferences. The suture is intended to aid in removal or repositioning during the initial stent placement procedure, to be used in the event of incorrect placement. The stent is available in either partially covered or fully covered configurations. The stent is covered with a silicone polymer to restrict tumor in-growth through the wire mesh and to occlude concurrent esophageal fistulas. The proposed stent is nearly identical in design to its predicate Agile Esophageal Stent System (K180144). The main difference between the proposed and the predicate stent is the type of delivery system used with the stent. The proposed Agile Esophageal OTW Stent is intended to be used with an over-the-wire delivery system, whereas the predicate Agile Esophageal Stent used a through-the-scope delivery system.

The over-the-wire delivery system is a co-axial tube design. The exterior tube is used to constrain the stent before deployment and to reconstrain the stent after partial deployment. The exterior tube has clear distal section so that the constrained stent is visible. A yellow transition zone on the inner tube of the delivery system is visible between the stent and the blue outer sheath. The system has RO and visual markers to aid in accurate stent placement.

The proposed delivery system is nearly identical to its predicate, WallFlex Esophageal Stent System (K091510/ K073266).

5. Indications for Use

The Agile Esophageal Partially Covered and Fully Covered OTW 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.

6. Technological Characteristics

The technological characteristics of the proposed Agile Esophageal OTW Stent system are nearly identical to its predicates. The stent component of the proposed system is nearly identical to Agile Esophageal Stent System (K180144). The key difference between the proposed Agile Esophageal OTW Stent system and the predicate device Agile Esophageal Stent System (K180144) is the delivery system, as the proposed Agile Esophageal OTW Stent system will be offered with an Over-the-Wire delivery system. Except for few minor design updates to the delivery system, the delivery system of the proposed device is nearly identical to the delivery system offered with WallFlex Esophageal Fully & Partially Covered Stent Systems (K091510 & K073266).

7. Substantial Equivalence

The proposed Agile Esophageal OTW stent has nearly identical design to its predicate device, Agile Esophageal Stent (K180144). The main difference between the two devices is the type of delivery system used for stent delivery. The proposed Agile Esophageal OTW Stent will utilize over-the-wire delivery system, whereas the predicate stent uses a through-the-scope delivery system.

The proposed Agile Esophageal over-the-wire delivery system is nearly identical to the delivery device used with WallFlex Esophageal Fully & Partially Covered Stent Systems (K091510 & K073266). Few minor design updates have been made to delivery device to accommodate its use with the proposed Agile Esophageal OTW Stent. These changes are to the reconstrainment band design, update to the exterior tube clear section and proximal inner section to accommodate different constrained stent length, and addition of additional laser marker bands to address user need requirement.

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

8. Performance Data

The product specifications of the proposed Agile Esophageal 23 mm OTW Stent are nearly identical to its predicate, Agile Esophageal 23mm Stent (K180144) and the product specifications of the proposed Agile Esophageal 23 mm OTW Delivery System are identical to WallFlex Esophageal Fully & Partially Covered Stent Systems (K091510 & K073266). The following bench testing was conducted to evaluate the changes on the proposed device. All Performance testing (bench) was successfully completed. The results of performance

(bench) testing demonstrate that the proposed Agile Esophageal OTW Stent System is considered substantially equivalent to the predicate devices.

Component	Product Specification	Result (Pass/Fail)
Delivery System	Visual Transition Zone Length	PASS
Delivery System	Reconstrainment Band to Distal Inner Bond	PASS
Delivery System and Stent	Delivery System Withdrawal / Removal	PASS
Delivery System and Stent	Deployment Force	PASS
Delivery System and Stent	Reconstrainment Force	PASS
Stent	Stent Hoop Expansion Force	PASS
Stent	Stent Hoop Compression Force	PASS
Stent	Stent Flexibility	PASS
Stent	Stent Fatigue Resistance	PASS
Stent	Cover Fatigue Resistance	PASS

Biocompatibility of the proposed Agile Esophageal OTW Stent System was evaluated in accordance with ISO 10993-1. A subset of tests was performed on the stent component, which included: Cytotoxicity, Irritation, Sensitization Testing. A complete set of biocompatibility testing was performed on over-the-wire delivery system, which included: Cytotoxicity, Irritation, Sensitization Testing. All acceptance criteria were met.

9. Conclusion

Boston Scientific has demonstrated that the proposed Agile Esophageal OTW Stent System is substantially equivalent to the currently marketed predicate devices.