July 10, 2026

Boston Scientific Corporation
Katherine Swanson
Sr. Regulatory Affairs Specialist
300 Boston Scientific Way
Marlboro, Massachusetts 01752

Re: K261978
Trade/Device Name: WallFlex Esophageal Stent System;Agile Esophageal Over-the-Wire (OTW) Stent System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: June 12, 2026
Received: June 12, 2026

Dear Katherine Swanson:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

510(k) Number *(if known)*
K261978

Device Name
WallFlex Esophageal Stent System;
Agile Esophageal Over-the-Wire (OTW) Stent System

Indications for Use *(Describe)*
The WallFlex 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.

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) Summary

1. Submitter

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2. Device:

Trade Name	WallFlex Esophageal Stent System Agile Esophageal Over-the-Wire (OTW) Stent System
Common Name	Esophageal Prosthesis
Classification Name	Prosthesis, Esophageal
Regulation Number	21 CFR 878.3610
Product Code	ESW
Classification	Class II

3. Predicate Device

Trade Name	WallFlex Esophageal Stent System
Common Name	Esophageal Prosthesis
Classification Name	Prosthesis, Esophageal
Clearance Number	K233939
Regulation Number	21 CFR 878.3610
Product Code	ESW
Classification	Class II

And

Trade Name	Agile Esophageal Over-the-Wire (OTW) Stent System

Common Name	Esophageal Prosthesis
Classification Name	Prosthesis, Esophageal
Clearance Number	K233837
Regulation Number	21 CFR 878.3610
Product Code	ESW
Classification	Class II

4. **Device Description:**

The WallFlex Esophageal Stent System consists of a self-expanding esophageal metal stent and a delivery system. The WallFlex Esophageal Stent is available partially or fully covered with silicone covering. The delivery system consists of a coaxial tubing assembly that constrains the stent on the delivery catheter shaft until the stent is released by retracting the exterior tube.

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 through-the-scope (TTS) delivery system and the 23mm diameter stent is pre-loaded on an 18.5Fr over-the-wire (OTW) delivery system. Only the 23mm diameter OTW configuration is in scope of this submission.

5. **Intended Use/Indications for Use:**

The WallFlex 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.

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.

6. **Indications for Use Comparison**

Both the proposed WallFlex Esophageal Stent System and Agile Esophageal OTW Stent System and the predicate devices WallFlex Esophageal Stent System (K233939) and Agile Esophageal OTW Stent System (K233837) have the same intended use/indication for use, respectively.

7. **Technological Comparison**

The delivery system catheter tip is transitioning from a manual glue process to an overmolded process. The glue will be removed as a patient-contacting material from the delivery catheter tip and minor changes will be made to the dimensional profile of the delivery catheter tip to support the new manufacturing process.

The proposed Agile Esophageal OTW System and WallFlex Esophageal Stent System are identical to the predicate Agile Esophageal OTW System (K233837) and WallFlex Esophageal Stent System (K233939) in intended use, indications for use, classification, principles of operation, technical characteristics, performance, and materials. The delivery catheter tip attachment process and dimensional changes do not raise different questions of safety and effectiveness. Non-clinical performance bench testing performed on the proposed Agile Esophageal OTW System and WallFlex Esophageal Stent demonstrates the devices are substantially equivalent.

Based on the Substantial Equivalence Decision-Making Process, the proposed devices may be considered substantially equivalent to the currently marketed WallFlex Esophageal Stent System (K233939) and Agile Esophageal OTW Stent System (K233837).

8. **Non-Clinical and/or Clinical Tests Summary & Conclusion**

Boston Scientific Corporation has demonstrated that the proposed Agile Esophageal OTW System and WallFlex Esophageal Stent System are substantially equivalent to the previously cleared and currently marketed WallFlex Esophageal Stent System (K233939) and Agile Esophageal OTW Stent System (K233837).

Non-clinical performance bench testing was performed on the proposed Agile Esophageal OTW System and WallFlex Esophageal Stent System. The following tests were performed on the devices with the proposed overmolded delivery catheter tips:

1. Trackability / Pushability
2. Delivery System Removal
3. Working Length
4. Tip to Inner Tube Bond
5. Delivery System Withdrawal
6. Guidewire Passage

All non-clinical performance bench testing met the predefined acceptance criteria with no failures or unexpected observations reported. The results demonstrate that the overmolded distal tip design continues to meet applicable Design Requirements and does not adversely affect device performance, safety, or function. These test results demonstrate that the devices with the overmolded delivery system tips are substantially equivalent to the commercial predicate WallFlex Esophageal and Agile Esophageal OTW Stent Systems.

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)].”

9. **Conclusion**

Boston Scientific has demonstrated that the proposed WallFlex Esophageal and Agile Esophagel OTW devices with overmolded delivery catheter tips may be considered

substantially equivalent to the currently marketed WallFlex Esophageal Stent System (K233939) and Agile Esophageal OTW Stent System (K233837).