



April 29, 2024

Boston Scientific
Yanine Garcia-Quezada
Principal Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K233939

Trade/Device Name: Ultraflex Esophageal NG Stent System; WallFlex Esophageal Stent System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: January 29, 2024
Received: January 30, 2024

Dear Yanine Garcia-Quezada:

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

Indications for Use

510(k) Number (if known)

K233939

Device Name

Ultraflex Esophageal NG Stent System

WallFlex Esophageal Stent System

Indications for Use (Describe)

The Ultraflex Esophageal NG Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only. The Ultraflex Esophageal NG Covered Stent System is also indicated for occlusion of concurrent esophageal fistula.

The WallFlex Esophageal Partially Covered and Fully Covered 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.

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510(k) Summary

Prepared on: 2023-12-14

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Boston Scientific
Applicant Address	300 Boston Scientific Way Marlborough MA 01752 United States
Applicant Contact Telephone	508-382-0240
Applicant Contact	Yanine Garcia-Quezada
Applicant Contact Email	yanine.garcia-quezada@bsci.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Ultraflex™ Esophageal NG Stent System WallFlex™ 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
K130004	Ultraflex Esophageal NG Stent System	ESW
K091510	WallFlex Esophageal Stent System	ESW

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Ultraflex Esophageal NG Stent System allows placement of a self-expanding metallic stent within the esophagus. The systems consist of a flexible delivery system preloaded with an expandable metallic stent available with or without a cover. The WallFlex Esophageal Stent System consists of a self-expanding esophageal metal stent and a delivery system.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Ultraflex Esophageal NG Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors only. The Ultraflex Esophageal NG Covered Stent System is also indicated for occlusion of concurrent esophageal fistula.

The WallFlex Esophageal Partially Covered and Fully Covered 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 Ultraflex™ Esophageal NG Stent System and WallFlex™ Esophageal Stent System devices are identical to their respective predicate devices.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The proposed Ultraflex Esophageal Stent System and WallFlex Esophageal Stent System devices are 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 Ultraflex Esophageal Stent System and WallFlex Esophageal Stent System are substantially equivalent to the previously cleared and currently marketed predicate Ultraflex Esophageal Stent System (K130004) and WallFlex Esophageal Stent System (K091510), respectively.

The proposed Ultraflex Esophageal Stent System and WallFlex Esophageal Stent System are identical to the predicate Ultraflex Esophageal Stent System (K130004) and WallFlex Esophageal Stent System (K091510) 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 Ultraflex Esophageal Stent System and WallFlex 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)]."