July 14, 2023

Boston Scientific Corporation
Lingling Guo
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K230269
Trade/Device Name: Ultraflex™ Tracheobronchial Stent System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal prosthesis
Regulatory Class: Class II
Product Code: JCT
Dated: June 16, 2023
Received: June 16, 2023

Dear Lingling Guo:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
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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.

Submission Number *(if known)*

K230269

Device Name

Ultraflex™ Tracheobronchial Stent System

Indications for Use *(Describe)*

The Ultraflex™ Tracheobronchial Stent System is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

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 for the Ultraflex™ Tracheobronchial Stent System

1. Submitter

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Date Prepared: June 6, 2023

2. Proposed Devices

Trade Name:	Ultraflex™ Tracheobronchial Stent System
Common Name:	Tracheal Prosthesis
Product Code:	JCT
Device Class and Panel:	Class II, General & Plastic Surgery
Classification Regulation:	21 CFR 878.3720

3. Predicate Devices

Trade Name:	Ultraflex™ Tracheobronchial Partially Covered Stent System
Clearance Number:	K141584
Common Name:	Tracheal Prosthesis
Product Code:	JCT
Device Class and Panel:	Class II, General & Plastic Surgery
Classification Regulation:	21 CFR 878.3720

Trade Name:	Ultraflex™ Tracheobronchial Uncovered Stent System
Clearance Number:	K121048
Common Name:	Tracheal Prosthesis
Product Code:	JCT
Device Class and Panel:	Class II, General & Plastic Surgery
Classification Regulation:	21 CFR 878.3720

4. Device Description

The Ultraflex Tracheobronchial Stent System is a permanently implanted expandable metal stent designed to serve as an intralumenal support to keep open the inner lumen of the tracheobronchial tree. They consist of a flexible delivery catheter preloaded with an expandable metallic stent.

The stent is an open-ended cylindrical mesh constructed from a single strand of nitinol wire. The wire is configured into a series of circumferential interwoven loops, with the number of loops being dependent on the diameter of the stent. The stent is elongated and compressed onto a plastic delivery catheter. The stent is held onto the delivery catheter by a crocheted nylon suture wrapped around the stent. The delivery catheter has a flush taper tip at the distal end, and a round hub handle at the proximal end.

The partially covered stent has a single layer of silicone that covers the midsection of the stent. Partially covered stents are available with a distal release system only. The distal release system begins stent deployment from the lower (distal) end of the delivery catheter. The uncovered stents are available with a distal or proximal release system.

The radiopaque (RO) markers on the delivery system and stent facilitate fluoroscopic placement.

The uncovered stent has one pair of RO markers indicated the approximate locations of the margins of the deployed stent. The partially covered stent has four (4) RO markers. The outer two (2) RO markers indicate the estimated final position of the ends of the deployed stent. The inner two (2) RO markers indicate the estimated final position of the margins of the deployed stent cover.

The delivery system accepts a 0.035 in (0.89 mm) or 0.038 in (0.97 mm) guidewire. The delivery system is passed over the guidewire into the tracheobronchial lumen. The stent is positioned appropriately using the RO markers for guidance under fluoroscopy and by bronchoscopic visualization of the stent.

5. Indications for Use

The Ultraflex™ Tracheobronchial Stent System is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

6. Technological Characteristics

The technological characteristics of proposed Ultraflex™ Tracheobronchial Stent System are identical to the predicate devices.

7. Substantial Equivalence

The Ultraflex™ Tracheobronchial Stent Systems do not have any change in material, design, specification, manufacturing technology, performance, biocompatibility or packaging to their respective predicate devices of Ultraflex™ Tracheobronchial Partially Covered Stent System (K141584) and Ultraflex™ Tracheobronchial Uncovered Stent System (K121048). The only change being introduced is to the MRI safety information in the Instruction for Use and the

addition of a Product Information for Patients and an implant card. The design requirements are not impacted by the labeling updates and the MRI safety status has not changed. Therefore, the subject devices are considered substantially equivalent to the predicate devices.

8. Performance Data

Performance testing (bench) was completed to demonstrate compliance to the FDA Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021. The testing included the following:

- Magnetically Induced Displacement Force
  ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*
- Magnetically Induced Torque
  ASTM F2213, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- Heating by Radio Frequency (RF) Fields
  ASTM F2182, *Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging*
- Image Artifact
  ASTM F2119, Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants

The performance (bench) testing demonstrated that the proposed Ultraflex™ Tracheobronchial Stent Systems comply with the FDA Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021 and are considered substantially equivalent to the predicate devices.

9. Conclusion

Boston Scientific Corporation has demonstrated that the proposed Ultraflex™ Tracheobronchial Stent Systems with updated labeling including MRI safety information are compliant with the FDA Guidance *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* issued on May 20, 2021, and substantially equivalent to the currently cleared predicate devices of Ultraflex™ Tracheobronchial Partially Covered Stent System (K141584) and Ultraflex™ Tracheobronchial Uncovered Stent System (K121048).