September 28, 2020

Boston Scientific Corporation
Catherine Sanford
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K201159
Trade/Device Name: WallFlex Colonic Stent System with Anchor Lock Delivery System
WallFlex Duodenal Stent System with Anchor Lock Delivery System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal prosthesis
Regulatory Class: II
Product Code: MQR, MUM

Dear Catherine Sanford:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 17, 2020. Specifically, FDA is updating this SE Letter, Indications for Use, and 510(k) trade names, which did match, as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Glenn Bell, (301) 796-6531, Glenn.Bell@fda.hhs.gov.

Sincerely,

Joyce Whang

for
Glenn B. Bell, Ph.D.
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

August 17, 2020

Boston Scientific Corporation
Catherine Sanford
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K201159
Trade/Device Name: WallFlex Colonic Stent System with Anchor Lock Delivery System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: MQR, MUM
Dated: July 16, 2020
Received: July 17, 2020

Dear Catherine Sanford:

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,

Daniel G. Walter Jr -S

Daniel G. Walter, Jr.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201159

Device Name
WallFlex Colonic Stent System with Anchor Lock Delivery System
WallFlex Duodenal Stent System with Anchor Lock Delivery System

Indications for Use *(Describe)*
The WallFlex Colonic Stent System with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstructions prior to colectomy in patients with malignant strictures.

The WallFlex Duodenal Stent System with Anchor Lock Delivery System is indicated for the palliative treatment of gastroduodenal obstructions 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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PRAStaff@fda.hhs.gov

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510(k) SUMMARY

1. **Submitter:**

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Contact: Catherine Sanford
Senior Regulatory Affairs Specialist
Telephone: 508-683-4498
E-mail: Catherine.sanford@bsci.com

Date Prepared: April 29th, 2020

2. **Proposed Device:**

Trade Name: Wallflex Colonic Stent System with Anchor Lock Delivery System
Classification Name: Expandable, metallic colonic stent
Regulation Number: 21 CFR 878.3610
Product Code: MQR
Classification and Panel: Class II, Gastroenterology/Urology

Trade Name: Wallflex Duodenal Stent System with Anchor Lock Delivery System
Classification Name: Expandable, metallic duodenal stent
Regulation Number: 21 CFR 878.3610
Product Code: MUM
Classification and Panel: Class II, Gastroenterology/Urology

3. **Predicate Device:**

Trade Name: Wallflex Enteral Colonic Stent with Anchor Lock Delivery System
Submitter / 510(k) Holder: Boston Scientific
Clearance Number: K061877
Classification Name: Expandable, metallic colonic stent
Regulation Number: 21 CFR 878.3610
Product Code: MQR
Classification and Panel: Class II, Gastroenterology/Urology

Trade Name: Wallflex Enteral Duodenal Stent with Anchor Lock Delivery System
Submitter / 510(k) Holder: Boston Scientific
Clearance Number: K062750

Classification Name: Expandable, metallic duodenal stent

Regulation Number: 21 CFR 878.3610
Product Code: MUM
Classification and Panel: Class II, Gastroenterology/Urology

4. Device Description:

The WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System each consist of two components: the implantable metal stent and the anchor lock delivery system.

The proposed stent is manufactured of Nitinol. The stent will be offered in two diameters, 22mm with a 27mm flare and 25mm with a 30mm flare. Each diameter will be available in three lengths, 6cm, 9cm, and 12cm. The WallFlex Duodenal Stent will only be offered in the 22mm/27mm stent diameter (all lengths) preloaded on the 230cm Anchor Lock Delivery System. The WallFlex Colonic Stent will be offered in the 22mm/27mm and 25mm/30mm diameters (all lengths) preloaded on the 230cm or 135cm Anchor Lock Delivery System. The Anchor Lock 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.

5. Indications for Use:

The WallFlex Colonic Stent System with Anchor Lock Delivery System is indicated for palliative treatment of colonic strictures caused by malignant neoplasms and to relieve large bowel obstructions prior to colectomy in patients with malignant strictures.

The WallFlex Duodenal Stent System with Anchor Lock Delivery System is indicated for the palliative treatment of gastroduodenal obstructions produced by malignant neoplasms.

The proposed Indications for Use are identical to the predicate devices Indications for Use.

6. Technological Characteristics

The only change introduced in this submission is to the surface finish of the nitinol wire. There is no impact to the technological characteristics as a result of this change as demonstrated by the biocompatibility testing (Section 15) and performance testing (Section 18).

7. Performance Data

<u>Bench Testing:</u>
The proposed WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System successfully passed all pre-defined product specifications for the tests performed. Below is a summary of the tests performed to show the proposed device satisfied all design verification requirements. In addition,

potentiodynamic testing and foreshortening was performed to address recent FDA guidance and to further support substantial equivalence. The results of this testing are passing.

Section	Test	Results (Pass/ Fail)
18.1	Deployment Force	Pass
18.2	Reconstrainment Force	Pass
18.3	Unconstrained Stent Length	Pass
18.4	Unconstrained Stent Diameter	Pass
18.5	Flare Diameter	Pass
18.6	Stent Hoop Force (Compression and Expansion)	Pass
18.7	Stent Fatigue Resistance	Pass
18.8	Stent Flexibility	Pass
18.9	Stent Corrosion Resistance	Pass

8. Conclusion

The information provided by Boston Scientific Corporation in this submission demonstrates that the proposed WallFlex Colonic Stent System with Anchor Lock Delivery System and WallFlex Duodenal Stent System with Anchor Lock Delivery System are substantially equivalent to the currently cleared Wallflex Enteral Colonic Stent with Anchor Lock Delivery System and Wallflex Enteral Duodenal Stent with Anchor Lock Delivery System (K061877, K062750).