



April 17, 2020

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

Re: K200257

Trade/Device Name: WallFlex Colonic Soft Stent System with Anchor Lock Delivery System,
WallFlex Duodenal Soft 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: February 27, 2020

Received: February 28, 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 Walter
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)

Device Name

WallFlex Colonic Soft Stent System with Anchor Lock Delivery System
WallFlex Duodenal Soft Stent System with Anchor Lock Delivery System

Indications for Use (Describe)

The WallFlex Colonic Soft 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 Soft 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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Section 6 510(k) Summary

1. Submitter

Boston Scientific Corporation
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Date Prepared: January 31st, 2020

2. Proposed Devices

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

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

3. Predicate Devices

Trade Name: WallFlex Enteral Colonic Stent System with Anchor Lock Delivery System
Manufacturer: Boston Scientific Corporation
Clearance Number: K061877
Common Name: Expandable, metallic colonic stent
Product Code: MQR
Device Class and Panel: Class II, Gastroenterology/Urology
Classification Regulation: 21 CFR 878.3610

Trade Name: WallFlex Enteral Duodenal Stent System with Anchor Lock Delivery System
Manufacturer: Boston Scientific Corporation
Clearance Number: K062750
Common Name: Expandable, metallic duodenal stent

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

Trade Name: Evolution Duodenal Stent System – Uncovered, Evolution Colonic Stent System - Uncovered

Manufacturer: Cook Ireland Ltd.

Clearance Number: K163468

Common Name: Expandable, metallic duodenal stent

Product Code: MUM, MQR

Device Class and Panel: Class II, Gastroenterology/Urology

Classification Regulation: 21 CFR 878.3610

4. Device Description

The WallFlex™ Colonic Soft Stent System with Anchor Lock Delivery System and WallFlex™ Duodenal Soft Stent System with Anchor Lock Delivery System each consist of two components: the implantable metal stent and the Anchor Lock Delivery System.

The stent is manufactured from Nitinol wires braided together to form a cylinder with a flared end. The wires are looped at both stent ends and welded at the non-flared end. The WallFlex Colonic Soft Stent and the WallFlex Duodenal Soft Stent will be offered in three diameters: 22 mm with a 27 mm flare, 20 mm with a 25 mm flare, and 18 mm with a 23 mm flare. Each diameter will be available in three lengths, 6cm, 9cm, and 12cm. The stent sizes that are shared between the WallFlex Colonic Soft Stent and the WallFlex Duodenal Soft Stent are identical in all aspects of their design; the only difference is in indication.

The stent is compressed on a flexible catheter for delivery. The delivery system consists in part of coaxial tubes. The exterior tube serves to constrain the stent until retracted during deployment. There are 3 radiopaque marker bands on the delivery system to facilitate placement; the exterior tube marker band, the deployment limit marker band, and the post deployment marker band. The exterior tube marker band is located adjacent to the leading end of the stent and the deployment limit marker band is located adjacent to the trailing end of the stent. The deployment limit marker band identifies the stent deployment limit, the point beyond which the stent cannot be reconstrained. The post deployment marker band, situated 4cm from the trailing end of the constrained stent, helps to facilitate accurate placement of the stent. The only design difference between the colonic and duodenal product offerings is how the stent is loaded onto the delivery system. The colonic stent is loaded with the flare is distal to the operator, and the duodenal stent is loaded with the flare is proximal to the operator.

The Anchor Lock stent holder is located at the trailing end of the stent and secures the stent on the delivery system to aid in reconstraint when repositioning the stent. The interior tube of the coaxial system contains a central lumen that accommodates a 0.035 in. / 0.89 mm guidewire. The device may be inserted through the working channel of a 9 French endoscope (minimum

channel diameter 3.2mm scope). The WallFlex Colonic/Duodenal Soft Stent with Anchor Lock Delivery System will be offered in 230cm.

5. Indications for Use

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

6. Technological Characteristics

The proposed WallFlex™ Colonic Soft Stent System with Anchor Lock Delivery System and WallFlex™ Duodenal Soft Stent System with Anchor Lock Delivery System share the same intended use, indications for use, and fundamental scientific technology as the predicate WallFlex Enteral Colonic/Duodenal Stent with Anchor Lock Delivery System cleared via K061877 and K062750 respectively. The only design difference between the colonic and duodenal product offerings is how the stent is loaded onto the delivery system. The proposed device and the predicate device share nearly identical technological characteristics, with the exception of wire diameter, loop design of stent ends, and delivery system diameter.

7. Performance Data

Performance testing (bench) was successfully completed to establish substantial equivalence between the proposed device and the predicate device. This testing included the following:

- Trackability/Pushability
- Marker Band Visualization
- Deployment Force
- Reconstraint Force
- Stent Reconstraint Percentage
- Withdrawal of Partially Deployed Stent
- Deployment Accuracy
- Bond Integrity
- Unconstrained Stent Length
- Unconstrained Stent Diameter
- Flare Diameter
- Stent Hoop Force (Expansion and Compression)
- Stent Fatigue Resistance
- Stent Flexibility
- Stent Corrosion Resistance
- Endoscope Compatibility – Device Outer Diameter
- Potentiodynamic
- Foreshortening
- Comparative Hoop Force (Expansion and Compression)

The results of non-clinical testing demonstrate that the proposed WallFlex Colonic/Duodenal Soft Stent System with Anchor Lock Delivery System is considered equivalent to the commercially available device and therefore safe and effective for its intended use.

8. Conclusion

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