June 15, 2023

Boston Scientific Corporation
Alexis Erazo
Principal Regulatory Affairs Specialist
200 Boston Scientific Way, Mail StopM41
Marlborough, MA 01752

Re: K223469
Trade/Device Name: WallFlex™ Biliary RX Stent System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
Dated: May 18, 2023
Received: May 18.2023

Dear Alexis Erazo:

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 and the limitations described below. 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.

The OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

1. The safety and effectiveness of this device for use in the vascular system has not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Office Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223469

Device Name

WallFlex Biliary RX Stent System

Indications for Use *(Describe)*

The WallFlex Biliary RX Stent system is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, and relief of malignant biliary obstructions prior to surgery.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5. 510(K) Summary

510(K) Summary [Per 21 CFR 807.92]

Submitter

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact:
Alexis Erazo
Principal Regulatory Affairs Specialist
508.382.0365
alexis.erazo@bsci.com

Date Prepared: November 16, 2022

Device Information

Trade name:	WallFlex™ Biliary RX Stent System
Device Common Name:	Biliary Catheter and Accessories
Classification Name:	Stents, Drains and Dilators for The Biliary Ducts
Regulation Number:	21 CFR 876.5010
Product Code:	FGE
Classification:	Class II
Panel:	Gastroenterology/Urology

Predicate Device Information

Trade name:	WallFlex™ Biliary RX Stent System
510(K) Number:	K140630
Device Common Name:	Biliary Catheter and Accessories
Classification Name:	Stents, Drains and Dilators for The Biliary Ducts
Regulation Number:	21 CFR 876.5010
Product Code:	FGE
Classification:	Class II
Panel:	Gastroenterology/Urology

Device Description

The WallFlex™ Biliary RX Stent System is an implantable biliary self-explaining metal stent that is pre-loaded onto a Delivery System with a working length of 194cm, which allows delivery of the stent into the Biliary system endoscopically. The self-expanding metal stent consists of Platinum cored Nitinol wires wound together to form a cylinder including flares on both the proximal and distal ends. WallFlex™ Biliary RX Stent is available uncovered, partially covered, or fully covered with a Permalume™ covering.

Indications for Use

The WallFlex Biliary RX Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, and relief of malignant biliary obstructions prior to surgery.

Technological Characteristics

The proposed WallFlex Biliary RX Stent System and the previously cleared and currently marketed predicate WallFlex Biliary RX Stent System (K140630) have similar technological characteristics. The variations between the proposed WallFlex Biliary RX Stent System and the predicate device are the covering configurations and the dimensions of the delivery system. The predicate WallFlex Biliary Stents are available in a 100mm length without a covering. The proposed WallFlex Biliary Stents are 100mm length in either a partial silicone covered (PC) configuration, or a full silicone covered (FC) configuration. The Permalume covering is identical to the predicate partially or fully covered devices available in a 40mm, 60mm and 80mm stent length.

The proposed 100mm PC and FC WallFlex Biliary Stent System use a slightly larger 9Fr delivery system as the covering adds additional volume of material requiring a delivery system with a slightly larger outer diameter. Although the French size is different, the materials, length and method of delivery is identical to the predicate.

Performance Data

Performance testing for the proposed WallFlex™ Biliary RX Stent System with 100mm Partially Covered (PC) and Fully Covered (FC) configurations was completed in accordance with the following FDA Guidance documents:

- *Metal Expandable Biliary Stents - Premarket Notification (510(k)) Submissions*, issued on July 27, 2019
- *Technical Considerations for Non-Clinical Assessment of Medical Devices Containing Nitinol*, issued on July 9, 2021
- *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment*, issued on May 20, 2021

Conclusion

Boston Scientific Corporation has demonstrated that the proposed WallFlex™ Biliary RX Stent System in 100mm PC and FC configurations are substantially equivalent to the previously cleared and currently marketed predicate WallFlex™ Biliary RX Stent System (K140630). 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)]."

The proposed and predicate devices have the same technological characteristics, indications for use, materials, and do not raise different questions of safety and effectiveness. The testing performed on the proposed WallFlex™ Biliary RX Stent System demonstrates the devices are substantially equivalent.