December 6, 2024

Boston Scientific
Alexis Erazo
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K242950
Trade/Device Name: WallFlex Biliary PLUS RX Stent System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: Class II
Product Code: FGE
Dated: September 23, 2024
Received: September 23, 2024

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 (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 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 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.

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 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.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Kellie B. Kelm -S

Kellie B. Kelm, Ph.D.
Acting 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242950

Device Name

WallFlex Biliary PLUS RX Stent System

Indications for Use *(Describe)*

The WallFlex Biliary PLUS RX Stent System is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms and relief of malignant biliary obstruction 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
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

Prepared on: 2024-11-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Boston Scientific
Applicant Address	100 Boston Scientific Way Marlborough MA 01752 United States
Applicant Contact Telephone	508.382.0365
Applicant Contact	Ms. Alexis Erazo
Applicant Contact Email	alexis.erazo@bsci.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	WallFlex Biliary PLUS RX Stent System
Common Name	Biliary catheter and accessories
Classification Name	Stents, Drains And Dilators For The Biliary Ducts
Regulation Number	876.5010
Product Code(s)	FGE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223469	WallFlex Biliary RX Stent System	FGE
K240464	WallFlex Biliary RX Stent System	FGE
K170740	VIABIL Short Wire Biliary Endoprosthesis	FGE

Device Description Summary

21 CFR 807.92(a)(4)

The WallFlex™ Biliary PLUS 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 hilar and duodenal ends. WallFlex™ Biliary PLUS RX Stent is available fully covered with a Permalume™ covering.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The proposed WallFlex™ Biliary PLUS RX Stent System and the predicate WallFlex™ Biliary RX Stent System (K240464; K223469) have the same intended use/indications for use.

Technological Comparison

21 CFR 807.92(a)(6)

The predicate WallFlex™ Biliary RX Stent System and proposed WallFlex™ Biliary PLUS RX Stent System have identical intended use,

principles of operations, materials and similar design specifications. The WallFlex Plus device design leverages the predicate WallFlex™ Biliary RX design with three (3) primary differences: (1) a reduced stent wire diameter, (2) a geometrically modified Hilar flare, and (3) a larger Duodenal flare.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Performance testing for the proposed WallFlex™ Biliary PLUS RX Stent System was completed in accordance with the following FDA Guidance documents to support substantial equivalence:
• 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 October 10, 2023

Boston Scientific Corporation has demonstrated that the proposed WallFlex Biliary PLUS RX Stent System is substantially equivalent to the previously cleared and currently marketed predicate WallFlex Biliary RX Stent System (K240464, K223469) and reference VIABIL® Short Wire Biliary Endoprosthesis (K170740).

The proposed WallFlex Biliary PLUS RX Stent System IS identical to the predicate WallFlex Biliary RX Stent System (K240464, K223469) in intended use, classification, principles of operation, and materials. The proposed WallFlex Biliary PLUS RX Stent System is identical to the reference VIABIL® Short Wire Biliary Endoprosthesis (K170740) in classification and principles of operation.

The differences between the proposed WallFlex Biliary PLUS RX device and the predicate WallFlex Biliary RX device do not raise different questions of safety and effectiveness. The testing performed on the proposed WallFlex Biliary PLUS RX 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)]."