August 30, 2024

Boston Scientific
Katherine Swanson
Sr. Regulatory Affairs Specialist
300 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K240464

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|---|---|
| Trade/Device Name: | WallFlex Biliary RX Stent System;<br>WallFlex Biliary RX Fully Covered Stent System RMV;<br>Epic Biliary Stent System |
| Regulation Number: | 21 CFR 876.5010 |
| Regulation Name: | Biliary Catheter and Accessories |
| Regulatory Class: | Class II |
| Product Code: | FGE, PNB |
| Dated: | July 31, 2024 |
| Received: | July 31, 2024 |

Dear Katherine Swanson:

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:

The safety and effectiveness of this device for use in 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.

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)*

K240464

Device Name

WallFlex Biliary RX Stent System ;
Epic Biliary Stent System;
WallFlex Biliary RX Fully Covered Stent System RMV

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 obstruction prior to surgery.

The WallFlex Biliary RX Fully Covered Stent System RMV is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, relief of malignant biliary obstruction prior to surgery and for indwell up to 12 months in the treatment of benign biliary strictures secondary to chronic pancreatitis.

The Epic Biliary Endoscopic Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

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.**

510(k) #: K240464

# 510(k) Summary

Prepared on: 2024-08-27

## Contact Details

21 CFR 807.92(a)(1)

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|---|---|
| Applicant Name | Boston Scientific |
| Applicant Address | 300 Boston Scientific Way Marlborough MA 01752 United States |
| Applicant Contact Telephone | 1 508-382-0281 |
| Applicant Contact | Ms. Katherine Swanson |
| Applicant Contact Email | katherine.swanson@bsci.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | WallFlex Biliary RX Stent System ;<br>Epic Biliary Stent System;<br>WallFlex Biliary RX Fully Covered Stent System RMV |
| Common Name | Biliary catheter and accessories |
| Classification Name | Stents, Drains And Dilators For The Biliary Ducts |
| Regulation Number | 876.5010 |
| Product Code(s) | FGE, PNB |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K140630 | WallFlex™ Biliary RX Stent System | FGE |
| DEN150040 | WallFlex™ Biliary RX Fully Covered Stent System RMV | PNB |
| K171809 | Epic™ Biliary Endoscopic Stent System | FGE |

## Device Description Summary

21 CFR 807.92(a)(4)

The WallFlex™ Biliary RX Stent System is available in the following stent configurations: Uncovered, Partially Covered, Fully Covered. The WallFlex Biliary RX Stent System consists of a self-expanding metal stent and a delivery system. The self-expanding metal stent consists of Platinum cored Nitinol wires wound together to form a cylinder including flares on both the proximal end and distal end.

WallFlex Fully Covered (FC) and Partially Covered (PC) Stents have a Permalume™ Coating, which is a translucent silicone polymer. The coating is used to reduce the potential for tumor in growth through the stent. The coating is used to reduce the potential for tumor in growth through the stent. The FC and PC stents have a retrieval loop for removal during the initial stent placement procedure, to be used in the event of incorrect placement.

The WallFlex Biliary RX Fully Covered Stent System RMV consist of a flexible delivery system preloaded with a self-expanding biliary metal stent. The stents are available in a fully covered configuration only, and have a Permalume™ Covering, which consists of a translucent silicone polymer, to reduce potential for tumor in growth through the stent. The stents also have a retrieval loop for removal during the initial stent placement procedure where the retrieval loop is used in the event of incorrect placement, or for removal following indwell up to 12 months.

The Epic™ Biliary Stent is a sterile laser cut self-expanding stent composed of a nickel titanium alloy. The stents are available uncovered

On both the proximal and distal ends of the stent, radiopaque markers increase visibility of the stent to aid in placement.

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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 obstruction prior to surgery.

The WallFlex Biliary RX Fully Covered Stent System RMV is indicated for use in the palliative treatment of biliary strictures produced by malignant neoplasms, relief of malignant biliary obstruction prior to surgery and for indwell up to 12 months in the treatment of benign biliary strictures secondary to chronic pancreatitis.

The Epic Biliary Endoscopic Stent System is indicated for palliation of malignant neoplasms in the biliary tree.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the proposed WallFlex Biliary RX Stent System, including RMV, and Epic Biliary Endoscopic Stent System devices are identical to their respective predicate devices.

## Technological Comparison 21 CFR 807.92(a)(6)

The proposed WallFlex Biliary RX Stent System, including RMV, and Epic Biliary Endoscopic Stent System devices are identical to the respective predicate device in design, material, chemical composition, fundamental technology, principle of operation, sterilization, packaging, shelf-life and manufacturing process.

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

Nonclinical Testing:
Radio Frequency Induced Heating
Magnetically Induced Displacement Force
Magnetically Induced Torque
Image Artifact Evaluation

Guidance Document :
Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses

Consensus Standards:
ASTM F2503 Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ASTM F2052 Measurement of Magnetically Induced Displacement Force
ASTM F2119 Evaluation of MR Image Artifacts from Passive Implants
ASTM F2182 Measurement of Radio Frequency Induce Heating on or Near Passive Implants
ASTM F2213 Measurement of Magnetically Induced Torque

Boston Scientific Corporation has demonstrated that the proposed WallFlex™ Biliary RX Stent System, WallFlex™ Biliary RX Fully Covered Stent System RMV, and Epic™ Biliary Stent System are identical to their predicates WallFlex™ Biliary RX Stent System (K140630), WallFlex Biliary RX Fully Covered Stent System RMV (DEN150040) and Epic™ Biliary Endoscopic (K171809).

The proposed WallFlex™ Biliary RX Stent System, WallFlex™ Biliary RX Fully Covered Stent System RMV, and Epic™ Biliary Stent System are identical to their respective predicates in intended use, indications for use, classification, principles of operation, technical characteristics, performance, and materials. The labeling changes do not raise different questions of safety and effectiveness. The testing performed on the proposed WallFlex™ Biliary RX Stent System, WallFlex™ Biliary RX Fully Covered Stent System RMV, and Epic™ Biliary Stent System demonstrates the devices are substantially equivalent to their respective predicate devices.

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)]."