June 17, 2026

Boston Scientific Corporation
Yingying Gao
Fellow, Regulatory Affairs
100 Boston Scientific Way
Marlboro, Massachusetts 01752

Re: K260428
Trade/Device Name: RIVOS™ EUS Access Device
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: ODG, KNS
Dated: May 15, 2026
Received: May 15, 2026

Dear Yingying Gao:

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. 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.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANTHONY LEE -S

Anthony Lee, Ph.D., MBA
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260428

Please provide the device trade name(s).

RIVOS™ EUS Access Device

Please provide your Indications for Use below.

The device is used to access and electrosurgically puncture the transgastric or transduodenal wall into the following: the intra- or extrahepatic bile ducts, or a pancreatic pseudocyst. The device is intended for use through the accessory channel of an ultrasound endoscope.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
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Date Prepared: February 9, 2026

2. Device:

Trade Name:	RIVOS™ EUS Access Device
Common Name:	Endoscope and accessories
Classification Name:	Endoscopic Ultrasound System, Gastroenterology-Urology
Regulation Number:	876.1500
Product Code:	ODG, KNS
Classification:	Class II

3. Predicate Devices:

Predicate device:

Trade Name:	EchoTip Ultra High Definition Ultrasound Access Needle
Common Name:	Gastroenterology-urology biopsy instrument
Classification Name:	Biopsy Needle
Manufacturer:	Cook Medical LLC

Clearance Number:	K092359
Regulation Number:	876.1075
Product Code:	FCG
Classification:	Class II

And

Predicate device:

Trade Name:	Cystotome Cystoenterostomy Needle Knife
Common Name:	Endoscopic electrosurgical unit and accessories
Classification Name	Unit, electrosurgical, endoscopic (with or without accessories)
Manufacturer:	Cook Medical LLC
Clearance Number:	K022595
Regulation Number:	876.4300
Product Code:	KNS
Classification:	Class II

4. Device Description:

Device Name: RIVOS™ EUS Access Device

The proposed RIVOS EUS Access Device is a sterile, single use ultrasound guided access device. The device comprises of a sharp contained within an access cannula, which facilitates puncture and access to a target structure. After sharp removal, a guidewire is placed through the access cannula and passed through to the desired location. The access cannula is contained within a flexible catheter with an electrosurgical tip that is advanced over the access cannula and guidewire for fistula creation.

The device is designed to be attached to the biopsy channel of a Curvilinear Array (CLA) Echoendoscope with a standard luer connection and delivered into the digestive tract. The device catheter length can be adjusted to accommodate different model echoendoscopes.

The RIVOS device has echogenic (visible under ultrasound) features at the distal end to facilitate real time visualization of the device under ultrasound.

The RIVOS device can be used with compatible BF Electrosurgical Generators: ERBE VIO® 3 or ERBE VIO® 300D and a Monopolar endoscopic cable with 3mm female plug.

5. Intended use/ Indications for Use:

The RIVOS EUS Access Device is used to access and electrosurgically puncture the transgastric or transduodenal wall into the following: the intra- or extra-hepatic bile ducts, or a pancreatic pseudocyst. The device is intended for use through the accessory channel of an ultrasound endoscope.

The Indications for Use statement of the RIVOS EUS Access Device is not identical to the predicate devices; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicates. Both the proposed and predicate devices have the same intended use for accessing and puncturing pancreacticobiliary anatomies or lesions from the gastrointestinal tract.

6. Technological Characteristics:

The RIVOS EUS Access Device performs initial puncture to access the target structure, allows for injection of contrast for visualization, facilitates guidewire passage and creation of a fistulous track using radio frequency (RF) energy. During puncture, the sharp and access cannula are advanced together as a single unit under ultrasound guidance. After access to the target structure is obtained, the sharp is removed from the device, leaving the access cannula within the target anatomy. A guidewire is inserted into the access cannula. Joined to the distal end of the catheter is an electrocautery tip, which contains a cutting electrode. The electrode can be activated by an electrosurgical generator and the electrocautery tip is advanced over the access cannula, creating a fistula for the passage of accessory devices.

It has the following technological characteristics:

- Secure scope attachment
- Adjustable sheath length and sheath locking mechanism
- Device Scope Passability
- Adjustable Device Extension Length
- Puncture into target structure
- Access a target structure
- Ability to maintain access
- Aspiration capability
- Contrast/Saline Injection Capability
- Guidewire Compatibility

- Device visibility under ultrasound
- Device visibility under fluoroscopy
- Fistula Creation with Electrocautery
- Ergonomic handle design

The RIVOS EUS Access Device shares similar design characteristics with its predicate device Cook EchoTip Ultra High Definition Ultrasound Access Needle. Both devices incorporate adjustable lengths of sheath for Ultrasound endoscope attachment and possess similar puncture component configurations. For the RIVOS device, initial puncture is achieved by advancing the sharp and access cannula into the target structure, whereas the Cook EchoTip Ultra needle utilizes advancement of its stylet and needle for puncture. Both devices offer echogenic visibility under ultrasound imaging, facilitating accurate initial puncture.

There are differences between the RIVOS device and Cook EchoTip Ultra needle. The minimum endoscope working channel for the RIVOS device is 3.7 mm, which is greater than the 2.0 mm minimum endoscope working channel specified for the Cook EchoTip Ultra needle. The RIVOS device is compatible with a 0.025" guidewire, while the Cook EchoTip Ultra needle accommodates a larger 0.035" guidewire. Additionally, the RIVOS device features a shorter extension length. These distinctions do not raise concerns regarding safety or effectiveness.

The RIVOS EUS Access Device exhibits design characteristics similar to its predicate device, the Cook Cystotome Cystoenterostomy Needle Knife. Both devices employ electrocautery for fistula creation and are compatible with monopolar electrosurgical generator(s) and 3 mm female plug monopolar endoscopic cables. Fistula formation is achieved via the diathermic ring on the outer catheter.

There are differences between the RIVOS device and Cook Cystotome. The RIVOS device features an 8Fr outer sheath with electrosurgical capabilities, whereas the Cook Cystotome utilizes a 10Fr outer sheath for cautery. In addition, the RIVOS device claims compatibility with multiple monopolar generators. These variations in outer sheath size and generator(s) compatibility do not raise questions of safety and effectiveness. A GLP Ex-Vivo Thermal Effects study of RIVOS device and Cook Cystotome device comparison was completed with all compatible generators on both high and low power settings and concluded a substantial equivalence between these two devices.

7. Performance Data:

Biocompatibility Testing:

The biocompatibility evaluation for the RIVOS EUS Access Device conducted in accordance with the FDA Guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff” (Issued on: September 8, 2023.), and ISO 10993-1 “ Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process” as recognized by FDA.

The RIVOS EUS Access Device is considered Surface Device: Breached or Compromised Surfaces Contact for a duration of less than 24 hours. The following tests were performed:

- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity
- Material mediated pyrogenicity
- Acute systemic toxicity

Electrical safety and Electromagnetic Compatibility (EMC)

Electrical safety and EMC testing were conducted on the RIVOS EUS Access Device. The RIVOS device, tested together with compatible generator(s) and Active Cord, complies with the IEC 60601-1, IEC 60601-1-6, IEC 60601-2-2 and IEC 60601-2-18 standards for safety. Additional Confirmatory Radiated Emissions testing was conducted to confirm electromagnetic compliance with the established test thresholds per IEC 60601-1-2 for EMC.

Performance Testing Summary:

Non-clinical performance bench testing was successfully completed to establish substantial equivalence between the proposed RIVOS EUS Access Device and its predicate devices Cook EchoTip Ultra Access Needle and Cook Cystotome.
The following tests were conducted on the RIVOS EUS Access Device:

1 Luer Interface
2 Scope Attachment Torsional Strength
3 Handle Tensile
4 Device Passability
5 Device Outer Diameter
6 Device Tip Flexibility
7 Device Extension Length
8 Sharp to Access Cannula Protrusion Length
9 Access Cannula Stiffness
10 Injection Force
11 Device Echogenicity
12 Device Radiopacity
13 Cautery Tip Dilation
14 Puncture Trajectory
15 Access Cannula Axial Compression
16 Image Quality
17 Access Cannula Kink Resistance
18 Access Cannula Lubricity
19 Device Durability
20 Sharp Removal Force
21 Puncture Force
22 Dilation Actuation Force
23 Handle Rotation
24 Adjustable Working Length
25 Guidewire Passability Force

A GLP Ex-Vivo Thermal Effects study of RIVOS device and Cook Cystotome device comparison was completed at all compatible generators on both high and low power settings and concluded a substantial equivalence between these two devices.

8. Conclusion:

Boston Scientific has demonstrated that proposed RIVOS EUS Access Device is substantially equivalent to the currently marketed Cook EchoTip Ultra High Definition Ultrasound Access Needle (K092359) and Cook Cystotome Cystoenterostomy Needle Knife (K022595).