October 27, 2023

Boston Scientific Corporation
Mr. Ian Broome
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K233318
Trade/Device Name: AXIOS Stent and Electrocautery-Enhanced Delivery System (6 mm x8 mm);
AXIOS Stent and Electrocautery-Enhanced Delivery System (8 mm x8 mm);
AXIOS Stent and Electrocautery-Enhanced Delivery System (10 mm x10 mm);
AXIOS Stent and Electrocautery-Enhanced Delivery System (15 mm x10 mm);
AXIOS Stent and Electrocautery-Enhanced Delivery System (20 mm x10 mm);
AXIOS Stent and Electrocautery-Enhanced Delivery System (15 mm x15 mm)
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: KNS
Dated: September 29, 2023
Received: September 29, 2023

Dear Mr. Ian Broome:

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 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,

Glenn B. Bell -S

Glenn B. Bell, Ph.D
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

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)*

K233318

Device Name

AXIOS Stent and Electrocautery-Enhanced Delivery System
(6mmx8mm) (M00553680);
AXIOS Stent and Electrocautery-Enhanced Delivery System (8mmx8mm) (M00553690);
AXIOS Stent and Electrocautery-Enhanced Delivery System (10mmx10mm) (M00553640);
AXIOS Stent and Electrocautery-Enhanced Delivery System (15mmx10mm) (M00553650);
AXIOS Stent and Electrocautery-Enhanced Delivery System (20mmx10mm) (M00553660);
AXIOS Stent and Electrocautery-Enhanced Delivery System (15mmx15mm) (M00553670)

Indications for Use *(Describe)*

6mmx8mm and 8mmx8mm stents: The AXIOS Stent and Electrocautery-Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, that are adherent to the gastric or bowel wall and are free of solid debris. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

10mmx10mm and 15mmx10mm stents: The AXIOS Electrocautery-Enhanced-Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size and walled-off necrosis ≥ 6 cm in size that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst or walled-off necrosis resolution. The AXIOS Stent and Electrocautery-Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of the gallbladder in patients with acute cholecystitis who are at high risk for surgery.

20mmx10mm and 15mmx15mm stents: The AXIOS Electrocautery-Enhanced Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size and walled-off necrosis ≥ 6 cm in size that are adherent to the gastric or bowel wall. Once placed, the AXIOS Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst or walled-off necrosis resolution.

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) Summary

Prepared on: 2023-10-26

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Boston Scientific Corporation |
| Applicant Address | 100 Boston Scientific Way Marlborough MA 01752 United States |
| Applicant Contact Telephone | +1 (508) 683-4000 |
| Applicant Contact | Mr. Ian Broome, M.S., RAC |
| Applicant Contact Email | ian.broome@bsci.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | AXIOS™ Stent and Electrocautery-Enhanced Delivery System (6mmx8mm) (M00553680);<br>AXIOS™ Stent and Electrocautery-Enhanced Delivery System (8mmx8mm) (M00553690);<br>AXIOS™ Stent and Electrocautery-Enhanced Delivery System (10mmx10mm) (M00553640);<br>AXIOS™ Stent and Electrocautery-Enhanced Delivery System (15mmx10mm) (M00553650);<br>AXIOS™ Stent and Electrocautery-Enhanced Delivery System (20mmx10mm) (M00553660);<br>AXIOS™ Stent and Electrocautery-Enhanced Delivery System (15mmx15mm) (M00553670) |
| Common Name | Endoscopic electrosurgical unit and accessories |
| Classification Name | Unit, Electrosurgical, Endoscopic (With Or Without Accessories) |
| Regulation Number | 876.4300 |
| Product Code | KNS |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| DEN230019, K22011 | AXIOS Stent and Electrocautery-Enhanced Delivery System | KNS |

## Device Description Summary

21 CFR 807.92(a)(4)

AXIOS™ Stent:
The AXIOS™ Stent is a flexible, MR conditional, fully-covered, self-expanding braided nitinol stent, which comes preloaded into a delivery system. The AXIOS™ stent is designed with two flanges on each end to prevent migration and to enable tissue plane apposition and a "saddle" in between the flanges to span the tissue implant distance.

Electrocautery-Enhanced Delivery System:
The AXIOS™ Electrocautery-Enhanced Delivery System consists of a catheter and an integrated handle with manual controls for positioning and deploying the AXIOS™ Stent. The AXIOS™ Electrocautery-Enhanced Delivery System is designed to be used in the gastrointestinal tract with commercially available echoendoscopes with a 3.7 mm diameter or larger working channel and is compatible with commercially available 0.035-inch insulated endoscopic guidewires.

The Electrocautery-Enhanced Delivery System connects with an off-the-shelf electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2.

The AXIOS™ Stent and Electrocautery-Enhanced Delivery System is provided sterile, disposable and intended for single use.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

6mmx8mm and 8mmx8mm stents: The AXIOS™ Stent and Electrocautery-Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, that are adherent to the gastric or bowel wall and are free of solid debris. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution.

10mmx10mm and 15mmx10mm stents: The AXIOS™ Electrocautery-Enhanced-Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size and walled-off necrosis ≥ 6 cm in size that are adherent to the gastric or bowel wall. Once placed, the AXIOS™ Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst or walled-off necrosis resolution.
The AXIOS™ Stent and Electrocautery-Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of the gallbladder in patients with acute cholecystitis who are at high risk for surgery.

20mmx10mm and 15mmx15mm stents: The AXIOS™ Electrocautery-Enhanced Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size and walled-off necrosis ≥ 6 cm in size that are adherent to the gastric or bowel wall. Once placed, the AXIOS™ Stent functions as an access port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst or walled-off necrosis resolution.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the proposed AXIOS™ Stent and Electrocautery-Enhanced Delivery System devices remain identical to the predicate device.

## Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics of proposed AXIOS™ Stent and Electrocautery-Enhanced Delivery System are identical to the predicate device.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Performance testing (bench) was completed to demonstrate equivalent settings for AXIOS devices when used with the ERBE VIO 3 Electrosurgical Unit (ESU).

The testing conducted was based on original clearance testing for the AXIOS Stent and Electrocautery-Enhanced Delivery System, along with consultation of the ESU manufacturer.

Two phases of ESU testing were performed:
• Range Finding, to establish ideal effect range based on baseline created with 300D ESU;
• Confirmation Testing, to determine ideal settings output and perform statistical analysis to ensure equivalent performance between both ESUs.

Based on the results of bench testing, the subject device is substantially equivalent to the predicates. The updates to labeling do not affect safety, effectiveness, performance or function of the device.