September 7, 2022

Boston Scientific Corporation
Ian Broome, M.S., RAC
Senior Regulatory Affairs Specialist
200 Boston Scientific Way, Mail Stop M41
Marlborough, MA 01752

Re: K220112
Trade/Device Name: AXIOS™ Stent and Electrocautery-Enhanced Delivery System
Regulation Number: 21 CFR§ 876.5015
Regulation Name: Pancreatic drainage stent and delivery system
Regulatory Class: II
Product Code: PCU, KNS
Dated: August 5, 2022
Received: August 5, 2022

Dear 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 (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 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.

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,

April Marrone, Ph.D., MBA
Acting 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

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)*

K220112

Device Name
AXIOS™ Stent and Electrocautery-Enhanced Delivery System

Indications for Use *(Describe)*

The AXIOS™ Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, and symptomatic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 1. 510(k) SUMMARY

510(k) SUMMARY
(per 21 CFR 807.92)

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Ian Broome, M.S., RAC
Senior Regulatory Affairs Specialist
Telephone: (617) 517-4932

Date Summary Prepared: 6 September 2022

2. Device:

Trade Name:	AXIOS™ Stent and Electrocautery-Enhanced Delivery System
Device Common Name:	Pancreatic drainage stent and delivery system & endoscopic electrosurgery device
Classification Name:	Pancreatic drainage stent and accessories & endoscopic electrosurgery accessories
Regulation Number:	21 CFR 876.5015, 21 CFR 876.4300
Product Code:	PCU/KNS
Classification:	Class II

3. Predicate Devices

Trade Name:	AXIOS™ Stent and Electrocautery-Enhanced Delivery System
510(k) Numbers:	K181905, K192043
Device Common Name:	Pancreatic drainage stent and delivery system & endoscopic electrosurgery device
Classification Name:	Pancreatic drainage stent and accessories and endoscopic electrosurgery accessories
Regulation Number:	21 CFR 876.5015 21 CFR 876.4300
Product Code:	PCU/KNS
Classification:	Class II

4. Device Description

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. Table 5-1 below discusses the main features of the AXIOS™ Stent and Electrocautery-Enhanced Delivery System.

Table 5-1. AXIOS™ Stent and Electrocautery-Enhanced Delivery System – Main Features

Component/Design	Feature Description
Catheter	• Provided sterile, for single-patient use • Working length: 138 cm • Outer Diameter 10.8 Fr • Fluoroscopy: AXIOS™ Stent is contained between two (2) Platinum Iridium Markers • Electrocautery Tip for precise cutting (in the Electrocautery-Enhanced Delivery System only) o Monopolar 750VP or 1500Vp-p Rated Accessory Voltage ⇨ IEC 60601-1 compliant
Handle	• Staged delivery system for precise stent placement ⇒Two (2)-step release of each flange, including a full "stop" ⇒Lock-out after the release of the first flange, preventing unintended deployment of the second flange
Guidewire Compatibility	0.035" insulated guidewires
Endoscope Compatibility	• Compatible with 3.7 mm diameter or larger working channel • Delivery system is Luer-locked to the proximal end of the biopsy port of the endoscope

Component/Design	Feature Description
Suggested Electrosurgical Unit or Generator (Electrocautery-Enhanced Delivery System only)	• Compliant to IEC 60601-1-2 and IEC 60601-2-2 o ERBE VIO 300D o ERBE ICC 200 o ERBE VIO 300S o ERBE VIO 200D
AXIOS™ Stent Design	• Bi-flange or double anchor for Staged and Precise positioning • Flange/anchor designed to: ⇒hold tissue layers in apposition ⇒prevent migration • MR Conditional • Provided sterile, for single-patient use
AXIOS™ Stent Lumen	• Large stent lumen diameter and short flow path/conduit to ⇒Facilitate passive efficient drainage ⇒Facilitate passage of endoscopic tools for assessment and treatment
AXIOS™ Stent Material	• Nitinol (Nickel-Titanium) ⇒Shape memory and superelasticity for controlled placement and optimal deployment ⇒Corrosion resistant and biocompatible
AXIOS™ Stent Covering	• Fully covered with Silicone ⇒Well tolerated by surrounding tissue to minimize tissue ingrowth ⇒Provides leak protection and minimizes tissue ingrowth allowing for atraumatic stent removal
AXIOS™ Stent Visualization	• The Stent is delivered constrained within a delivery system and deployed under visualization ⇒EUS confirmation of first flange deployment ⇒Direct endoscopic or EUS viewing of second flange deployment ⇒Radiopacity of Nitinol allows fluoroscopy of deployed stent

5. Proposed Indications for Use

The AXIOS™ Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, and symptomatic 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.

6. Technological Characteristics

The technological characteristics of the device remain unchanged from the predicates cleared in K181905 (the 10mm x 10 mm, 15mm x 10mm and 20mm x 10mm stent sizes) and K192043 (the 15mm x 15mm stent size).

7. Performance Data

The devices' technological characteristics remain unchanged, therefore, no further performance testing was required.

8. Clinical Data Summary

Clinical data from a prospective, single arm, multi-center trial on the AXIOS™ Stent and Electrocautery-Enhanced Delivery System support the expanded indication for use and confirm the subject device's substantial equivalence, safety and effectiveness to the predicate. The trial was conducted per GCP and 21 CFR Parts 50, 56 and 812 under an approved Investigational Device Exemption.

Patients with Walled Off Necrosis (WON) with greater than 30% necrotic material (as suggested by pre-operative imaging) were eligible for inclusion. The primary effectiveness endpoint was resolution of WON with endoscopic drainage (defined as radiographic decrease of WON size to ≤ 3cm evaluated by CT scan or MRI within 60 days from AXIOS™ stent placement). The primary safety endpoint was AXIOS™ stent-related or WON drainage procedure-related serious adverse events (SAE).

Forty patients enrolled in the study. Forty-five AXIOS™ stents were implanted in 40 subjects (some subjects had multiple WON). Post procedural radiographic evidence demonstrated successful resolution of WON in 97.5% (39/40) patients. Table 5-1 below shows the Primary Effectiveness Endpoint, Primary Safety Endpoint, and Additional Endpoints.

Table 5-2. Primary Effectiveness and Safety Endpoints and Additional Endpoints

	ITT Subjects (N=40)
Primary Effectiveness Endpoint	
• Resolution of WON to ≤ 3 cm (assessed radiographically by CT scan or MRI within 60 days from AXIOS™ stent placement)[1]	97.5% (39/40) [86.8%, 99.9%]
Primary Safety Endpoint	
• AXIOS™ stent related or WON drainage procedure related serious adverse events	7.5% (3/40) [1.6%, 20.4%]
Additional Endpoints	
• Reduction of WON-related symptoms	
○ Final WON assessment visit	75.0% (30/40)
○ 6-month WON recurrence assessment visit	85.3% (29/34)
• Technical success	

○ AXIOS™ stent placement	100.0% (40/40)
○ AXIOS™ stent removal	100.0% (40/40)
• Drainage procedure time (min)	
○ Total	22.6±11.3 (40) (1.0, 51.0)
○ Initial AXIOS™ stent	21.8±11.0 (40) (1.0, 51.0)
○ Second AXIOS™ stent	10.0±3.5 (3) (8.0, 14.0)
• Resolution of WON by 6-month post-stent removal[2] ○ Resolution before AXIOS™ removal – not lost to 6-month follow-up (34/34) ○ Resolution before AXIOS™ removal – lost to 6-month follow-up (6/6)	100.0% (40/40)
• Time to WON resolution of ≤ 3 cm (days)	34.1±16.8 (40) (4.0, 100.0)
• Recurrence of WON from initial resolution to 6 months post-AXIOS™ stent removal	0.0% (0/34)
• Stent lumen patency	
○ Drainage through AXIOS™ stent visualized from the stomach or bowel	
▪ After stent placement	100.0% (40/40)
▪ Before stent removal	65.0% (26/40)
• Visual confirmation of AXIOS™ stent lumen patency	
○ After stent placement	100.0% (40/40)
○ Before stent removal	97.5% (39/40)
• Fluoroscopy time per endoscopic procedure (min)	4.6±6.1 (38) (1.0, 33.0)
• Incidence of new organ failure from drainageprocedure to WON resolution[3]	2.6% (1/39)
• Change of SF-12 score from baseline to:	
○ AXIOS™ stent removal[4]	23.6±20.5 (37) (-26.1, 67.2)
○ End of study[5]	40.9±24.3 (27) (-12.5, 81.3)

[1] One subject reached WON size <3cm 100 days after AXIOS™ stent placement.
[2] All subjects (including those that were later lost to follow-up) had resolution of WON by 100 days after AXIOS™ stent placement and before AXIOS™ stent removal, i.e. by 6 month post-stent removal.
[3] Organ failure assessment not collected for 1 subject.
[4] SF-12 not collected for 3 subjects at time of stent removal.
[5] SF-12 not collected for 7 subjects at 6-month WON assessment visit.

The observed proportion of subjects who were positive for the Primary Safety Endpoint for the ITT cohort was 7.5% (3/40; 95% CI 1.6% to 20.4%).

There were no unanticipated adverse device effects reported in this study. There were 49 adverse events (AEs) observed in 24 subjects since the beginning of the study. Of the 49 adverse events, 36 were recorded as Serious Adverse Events (SAEs). Five AEs were related to the AXIOS™ stent and 7 AEs were related to a necrosectomy. There were no AEs related to the use of the Advanix™ 7Fr double pigtail plastic stent. Two (2) SAEs were reported as possibly AXIOS™-related or WON procedure-related and 4 SAEs were reported as related to necrosectomy.

9. Conclusion

Based on the clinical investigation results, technological characteristics, and prior nonclinical testing performed on the identical predicate device, the AXIOS™ Stent and Electrocautery-Enhanced Delivery System has been shown to be safe, effective, and substantially equivalent to the predicate device when indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6cm in size, and symptomatic Walled Off Necrosis ≥ 6cm in size, that are adherent to the gastric or bowel wall.

In addition to the clinical evidence, labeling and other materials provided in this 510(k) premarket notification submission demonstrate compliance to the special controls prescribed in 21 CFR 876.5015.