April 15, 2021

Boston Scientific Corporation
Aparna Philip
Regulatory Affairs Specialist II
100 Boston Scientific Way
Marlborough, MA 01752

Re: K203132
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: March 15, 2021
Received: March 16, 2021

Dear Aparna Philip:

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,

Je An -S Digitally signed by Je An -S

Je Hi An, Ph.D.
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)*
K203132

Device Name
AXIOS™ Stent and Electrocautery-Enhanced Delivery System

Indications for Use *(Describe)*
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.

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.

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SECTION 5: 510(K) SUMMARY

510(k) SUMMARY

1. **Submitter:**

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Aparna Philip
Regulatory Affairs Specialist II
Telephone: 508-382-0259
E-mail: Aparna.Philip@bsci.com

Date Prepared: October 16, 2020

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 Delivery System
Regulation Number:	21CFR 876.5015 21CFR 876.4300
Product Code:	PCU/ KNS
Classification:	Class II

3. **Predicate Device**

Trade Name:	AXIOS™ Stent and Electrocautery-Enhanced Delivery System & AXIOS Stent and Delivery System
510(k) Number:	K181905
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:	21CFR 876.5015 21CFR 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 the 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 Electrocautery-Enhanced Delivery System • Outer Diameter 9 Fr • Fluoroscopy: AXIOS Stent is contained between two (2) Platinum Iridium Markers • Electrocautery Tip for precise cutting • 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
Electrosurgical Unit or Generator	• Select an electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2. Recommended electrosurgical units or generators include: ○ ERBE VIO 300D ○ ERBE ICC 200 ○ ERBE VIO 300S ○ 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	• Stent lumen diameter and short flow path/conduit to ⇒Facilitate passive efficient pseudocyst drainage
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. Indications for Use:

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.

6. Technological Characteristics

The proposed AXIOS Stents (6 mm x 8 mm and 8 mm x 8 mm) and Electrocautery-Enhanced Delivery System retains similar performance compared to the predicate AXIOS Stent (10 mm x 10 mm) despite the dimensional differences of the stent and delivery system. The intended use, and over all mode of operation remains identical to the predicate AXIOS Stent and Electrocautery-Enhanced Delivery system cleared via K181905.

7. Performance Data

The proposed AXIOS Stent and Electrocautery-Enhanced Delivery System successfully passed all pre-defined product specifications for the tests performed. Below is a summary of the tests performed to show the proposed device satisfied all design verification and validation requirements.

Table 5-2 Summary of Bench Tests and Results

Test	Results (Pass/ Fail)
AXIOS Stent	
Deployed Stent Saddle Length	Pass
Deployed Stent Saddle Outer Diameter	Pass
Deployed Stent Flange Width	Pass
Stent Pull-out Force	Pass
Stent (Saddle) Radial Strength –in compression & expansion	Pass
Deployment Force	Pass
Implant Anchor Function- Retention (tensile)	Pass
Magnetic Resonance Testing	Pass
Fatigue Testing	Pass
AXIOS 9 Fr. Electrocautery-Enhanced Delivery System	
Delivery System Working Length	Pass
Catheter Extension	Pass
Nose Lock Hold Force	Pass
Slider Lock Hold Force	Pass
Nose Lock Cycling	Pass
Slider Lock Cycling	Pass
Distal Pusher Catheter to Distal Nose Joint Strength	Pass
Pusher Catheter to Hypotube Joint Strength	Pass
Outer Sheath to Hypotube Joint Strength	Pass
Pusher Hypotube to Handle Joint Strength	Pass
Outer Sheath Hypotube to Handle Joint Strength	Pass

Distal Pusher to Proximal Pusher Catheter Joint Strength	Pass
Outer Sheath to Handle Torque Strength	Pass
Luer to Nose Joint Strength	Pass
Tracking Force	Pass

Conclusion

The information Boston Scientific Corporation provided in this submission demonstrates that the proposed AXIOS 6 mm x 8 mm and 8 mm x 8 mm Stent and Electrocautery-Enhanced Delivery System is substantially equivalent to the currently cleared AXIOS 10 mm x 10 mm Stent and Electrocautery-Enhanced Delivery System K181905.