March 25, 2019

Boston Scientific Corporation
Kayla Mackey
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K181905
Trade/Device Name: AXIOS Stent and Delivery System, 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: February 25, 2019
Received: February 26, 2019

Dear Kayla Mackey:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark J. Antonino -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
Unknown K181905

Device Name
AXIOS Stent and Delivery System
AXIOS Stent and Electrocautery Enhanced Delivery System

Indications for Use *(Describe)*
The AXIOS Stent and Delivery System & AXIOS Stent and Electrocautery Enhanced Delivery System are 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, with ≥70% fluid content, 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 5. 510(K) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Kayla Mackey
Regulatory Affairs Specialist
Telephone: 508-683-4534
Fax: 508-683-5939

Date Prepared: July 13, 2018

2. Device:

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

Trade Name:	AXIOS™ Stent and Delivery System
Device Common Name:	Pancreatic drainage stent and delivery system
Classification Name:	Pancreatic drainage stent and delivery system
Regulation Number:	21CFR 876.5015
Product Code:	PCU
Classification:	Class II

3. Predicate Device

Trade Name:	AXIOS™ Stent and Electrocautery-Enhanced Delivery System & AXIOS™ Stent
510(k) Number:	K153088/ K163272
Device Common Name:	Pancreatic drainage stent and delivery system & endoscopic electrosurgical unit and accessories
Classification Name:	Pancreatic drainage stent and delivery system and endoscopic electrosurgical unit and accessories
Regulation Number:	21CFR 876.5015 21CFR 876.4300
Product Code:	PCU/ KNS
Classification:	Class II

Trade Name:	AXIOS™ Stent and Delivery System
510(k) Number:	K153088
Device Common Name:	Pancreatic drainage stent and delivery system
Classification Name:	Pancreatic drainage stent and delivery system
Regulation Number:	21CFR 876.5015
Product Code:	PCU
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.

Non-Cautery Enhanced Delivery System:

The stent is preloaded within the AXIOS delivery catheter. The Delivery System consists of a catheter and an integrated handle with manual controls for positioning and deploying the AXIOS stent. The Delivery System is designed to be used in the gastrointestinal tract in conjunction 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.

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 Sten. 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 Delivery System- Main Features

Component/Design	Feature Description

Catheter	• Provided sterile, for single-patient use
	• Working length:
	  ○ 138 cm Electrocautery Enhanced Delivery System
	  ○ 139 cm Non-cautery Delivery System
	• Outer Diameter 10.8 Fr
	• Fluoroscopy: AXIOS Stent is contained between two (2) Platinum Iridium Markers
	  ○

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
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. Indications for Use:

The AXIOS Stent is 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, with ≥70% fluid content, 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 proposed AXIOS Stent is equivalent to the predicate AXIOS stent. A manufacturing change was made to remove the passivation/etching manufacturing step. This change was documented internally. The purpose of this 510(k) is to reinstate this manufacturing step. There are no changes to the delivery system for either the electrocautery-enhanced version or the non-electrocautery enhanced version. The stent dimensions and materials, intended use, delivery system, and mode of operation remains identical to the predicate AXIOS Stent and Electrocautery Enhanced Delivery system and AXIOS Stent and Delivery System cleared via K153088 & K163272.

7. Performance Data

Bench Testing:

The proposed passivated AXIOS Stent successfully passed all pre-defined product specifications and is equivalent to the predicate passivated AXIOS stent for the tests performed. There are no changes to the delivery system or the stent dimensions for the current AXIOS stents. Below is a summary of the tests performed to show the proposed device satisfied all design verification and validation requirements.

	Test	**Results (Pass/ Fail)**
1	Deployed Stent Saddle Length	Pass
2	Deployed Stent Saddle Outer Diameter	Pass
3	Deployed Stent Flange Width	Pass
4	Corrosion Testing via ASTM Standard F2129 *Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices*	Pass
5	Stent Fatigue	Pass
6	Stent Radial Strength –in expansion & in compression	Pass
7	Stent Deployment Force	Pass

8. Biocompatibility Testing:

The proposed AXIOS Stent is equivalent to the predicate AXIOS stent. A manufacturing change was made to remove the passivation/etching manufacturing step. This change was documented internally. The purpose of this 510(k) is to reinstate this manufacturing step. There are no changes to the delivery system for either the electrocautery-enhanced version of the non-electrocautery enhanced version. The predicate biocompatibility testing conducted per EN ISO 10993-1 continues to be representative of the proposed AXIOS stent and delivery systems. Boston Scientific did conduct a Cytotoxicity test on the final finished stent as a screening test to ensure the manufacturing change did not impact the toxicity of the device.

Conclusion

The purpose of this 510(k) is to reinstate the passivation/etching manufacturing step for the AXIOS stents. The manufacturing change to the passivation/etching step has been reinstated and remains identical to the predicate AXIOS device cleared via K153088 and K163272. The information Boston Scientific Corporation provided in this submission demonstrates that the proposed AXIOS Stent is substantially equivalent to the currently cleared AXIOS Stents cleared via K153088 & K163272.