DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 18, 2017

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

Re: K163272
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: November 18, 2016
Received: November 23, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Unknown K163272

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 ≥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:

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Date Prepared: November 18, 2016

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 and endoscopic electrosurgery accessories
Regulation Number:	21CFR 876.5015 21CFR 876.4300
Product Code:	Primary Code: PCU Secondary Code: KNS
Classification:	Class II

3. Predicate Device

Trade Name:	AXIOS™ Stent and Electrocautery-Enhanced Delivery System
510(k) Number:	K153088
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:	Primary Code: PCU Secondary Code: 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 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 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 10.8 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 o 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	• 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. 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 (20mm x 10mm) and Electocautery Enhanced Delivery System is identical to the predicate AXIOS Stent (15mm x 10mm) and Electrocautery Enhanced Delivery System with the exception of the stent size. The proposed AXIOS Stent has a stent lumen diameter of 20 mm and a stent flange diameter of 29 mm. There are no changes to the delivery system. The intended use, electrocautery enhanced delivery system, and mode of operation remains identical to the predicate AXIOS Stent and Electrocautery Enhanced Delivery system cleared via K153088.

7. Performance Data

Bench Testing:

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.

	Test	**Results (Pass/ Fail)**
1	Deployed Stent Saddle Length	Pass
2	Deployed Stent Saddle Outer Diameter	Pass
3	Deployed Stent Flange Width	Pass
4	Stent Pull-out Force (tensile)	Pass
5	Stent (Saddle) Radial Strength –in expansion	Pass
6	Stent (Saddle) Radial Strength –in compression	Pass
7	Tracking Force	Pass
8	Stent Fatigue	Pass
9	Stent Deployment Force	Pass
10	Implant Anchor Function- Retention (tensile)	Pass
11	MR Testing	Pass

Animal Testing:

The safety and performance of the proposed AXIOS Stent and Electrocautery Enhanced Delivery System was also evaluated in animal models. The proposed device performed as intended and did not raise any new issues of safety or performance.

Clinical Literature Review:

Clinical data was collected through a clinical literature review which evaluated the performance of larger diameter metal stents (≥20mm) for treatment of Walled off Pancreatic Necrosis. The conclusion of the analysis demonstrated that the clinical success of the larger diameter stents was similar to the success rates offered in the IDE for the 10mm and 15mm stent sizes. In addition,

there was no increased risk for stent migration as the stent flange diameter was increased to compensate for the increased stent lumen diameter. The larger stent lumen diameter enhances drainage of Walled off Necrosis and can also ease the of passage of associated endoscopic devices. The clinical literature, referenced in this submission, did not identify any new risks associated with larger diameter metal stents. In conclusion, BSC believes that the safety and effectiveness of a larger diameter metal stent like the proposed AXIOS 20mm Stent is comparable to the currently cleared AXIOS Stents.

Conclusion

The information Boston Scientific Corporation provided in this submission demonstrates that the proposed AXIOS 20 mm Stent and Electrocautery Enhanced Delivery System is substantially equivalent to the currently cleared AXIOS Stent and Electocautery Enhanced Delivery System K153088.