DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 5, 2015

Boston Scientific Corporation
Carole Sykes
V.P. Clinical and Regulatory Affairs
453 Ravendale Drive, Suite H
Mountain View, CA 94043

Re: K150692
Trade/Device Name: AXIOS™ Stent with 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: April 29, 2015
Received: June 24, 2015

Dear Carole Sykes,

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 yours,

Herbert P. Lerner -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)*

K150692

Device Name
AXIOS Stent with Electrocautery Enhanced Delivery System

Indications for Use *(Describe)*

The AXIOS Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 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 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)

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510(K) SUMMARY

Date Prepared:	March 17, 2015
Submitter:	Boston Scientific Corp.
Address:	453 Ravendale Drive, Suite H, Mountain View, CA 94043
Phone:	(650) 868-4331
Fax:	(650) 961-9901
Contact Person:	Carole Sykes VP Clinical and Regulatory Affairs
Trade Name/Proprietary Name:	AXIOS Stent with Electrocautery Enhanced Delivery System
Class:	II
Common Name:	Pancreatic drainage stent and delivery system and endoscopic electrosurgery device
Classification/Name:	Pancreatic drainage stent and accessories and endoscopic electrosurgery accessories
Regulation:	21 CRF 876.5015 / 21 CFR 876.4300
Product Code:	PCU / 78KNS
Predicate Devices (Legally marketed devices to which substantial equivalence is claimed):	Xlumena, Inc. AXIOS Stent and Delivery System K140561 and K123250 Wilson-Cook Medical, Inc. Wilson-Cook Cystotome K022595

I. Device Description:

The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the endoscopic placement of a flexible, MR conditional, fully-covered, self-expanding braided Nitinol stent for transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts. The AXIOS Stent with Electrocautery Enhanced Delivery System is comprised of two main components: (1) AXIOS Stent and (2) Electrocautery Enhanced Delivery System.

The subject premarket notification describes modifications to the cleared AXIOS Delivery System to add electrocautery to facilitate precise access to anatomic targets as well as the staged placement of the currently cleared AXIOS Stent. The AXIOS Stent with Electrocautery Enhanced Delivery System incorporates the same identical implantable stent that is preloaded within the current AXIOS Delivery System (K123250). Both the AXIOS Stent and Delivery System were originally cleared under 510(k) K123250 and most recently under 510(k) K140561.

As with the non-cautery AXIOS devices, the Electrocautery Enhanced AXIOS Delivery System is compatible with commercially-available 0.035-inch endoscopic guidewires and intended to be used in the gastrointestinal tract in conjunction with commercially-

available echoendoscopes. The Electrocautery Enhanced Delivery System has been modified to connect with an off-the- shelf electrosurgical unit or generator that is compliant to IEC 60601-1-2 and IEC 60601-2-2. The generator must be installed and put into service according to the EMC information provided in the generator manufacturer's guidance and declaration for electromagnetic compatibility.

Cables and patient return electrodes that are specified by generator manufacturer must be used for connection.

The AXIOS Stent with Electrocautery Enhanced Delivery System is provided sterile, disposable and intended for single use. The Electrocautery Enhanced AXIOS Delivery System is IEC compliant.

II. Indications for Use:

The AXIOS™ Stent with Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 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 resolution.

III. Summary of Technological Characteristics of the Proposed Device Compared to the Predicate Device:

The AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the legally marketed predicate devices identified in Table 1. The AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent in terms of intended use / indications for use, technological characteristics and principles of operation to the predicate AXIOS Stent and Delivery System which was cleared by FDA in 510(k)s K123250 and K140561, and the Wilson-Cook Medical Cystotome cleared by FDA in 510(k) K022595.

Table 1. Comparison of AXIOS Stent with Electrocautery Enhanced Delivery System with Predicate Devices

Feature			
	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	**PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System**	**REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome**
510(k) Number	K150692	K140561and K123250	K022595

Feature	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System	REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome
Indications for Use	To facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 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 resolution.	Same	For use as an electrosurgical accessory to cannulate the transgastric or transduodenal wall and into a pancreatic pseudocyst that is visibly bulging into the gastrointestinal tract.
Class	II	Same	Same
Classification/ Regulation Name	Pancreatic drainage stent and accessories and endoscopic electrosurgery accessories	Pancreatic drainage stent and accessories	Endoscopic electrosurgery accessories
Regulation Number	21CFR 876.5015 21CFR 876.4300	21CFR 876.5015	21CFR 876.4300
Product Code	PCU and 78KNS	PCU	78KNS
Outer Catheter Length	138 cm	Same	165 CM
Inner Catheter Sheath Diameter	9 Fr with preloaded Stent	Same	5 Fr with 0.038” needle knife
Guidewire Compatibility	0.035”	Same	Same
Endoscope Compatibility	Compatible with 3.7 mm diameter or larger working channel	Same	Same
Placement Site	Transgastric or transduodenal wall and into a pancreatic pseudocyst	Same	Same
Pseudocyst Size	≥ 6cm in size	Same	≥ 4cm in size

Feature	SUBJECT DEVICE AXIOS Stent with Electrocautery Enhanced Delivery System	PRIMARY PREDICATE DEVICE Xlumena AXIOS Stent with (non-cautery) Delivery System	REFERENCE PREDICATE DEVICE Wilson-Cook Medical Wilson-Cook Cystotome
Mode of Access or Operation	Electrosurgically punctures hole at the placement site. Fine wire electrocautery element (0.006" SS wire); electrosurgically active wire using pure cutting current to access pseudocyst. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Access path at placement site is created using conventional access tools. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Electrosurgically punctures hole at the placement site. Needle 0.038" knife tip; electrosurgically active knife using pure cutting current to access pseudocyst. Enlarge incision with a cauterizing diathermic ring and 10 Fr outer catheter. Utilizes a 0.035" wire for placement of a stent or drainage kit via compatible endoscope.
Stent Deployment Mechanism	Deployed via handle controls. Distal stent flange first followed by the proximal flange.	Same	N/A
Cutting Current	80-120 Watts	N/A	80-120 Watts
Sterilization Method	EO	EO	EO

IV. Summary of the Nonclinical Tests Performed:

Nonclinical testing performed includes: Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety, and Animal Testing. The nonclinical test results demonstrate that the modified device continues to meet product design specifications.

1. Bench Performance

Bench performance testing was conducted for the AXIOS Stent with Electrocautery Enhanced Delivery System to demonstrate that the modified delivery system continues to meet the requirements of the product design specification and perform in accordance with its intended use. There have been no design or material changes to the AXIOS Stent; it is identical to the AXIOS Stent cleared in K123250 and K140561. The bench performance testing was conducted for the modifications to the Electrocautery Enhanced Delivery System Catheter and Handle only and included the following testing:

- RF Compatibility / Safety
- Tensile Strength testing
- Unsheathing Force (Distal Flange)
- Effect of Retainer (Stent Retention Force)

- Design Validation Testing
- Transportation and Conditioning Testing
- Shelf Life and Package Testing
- Magnetic Resonance testing was confirmed via ASTM F2052-14, ASTM F2213-06, ASTM F2182-11a and ASTM F2119-13.

Where applicable, performance testing was conducted in accordance with the following standards:

- ISO 10555-1:2013 - *Sterile, single-use intravascular catheters Part 1. General requirements*
- ISO 594-1:1986 - *Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Part 1 : General Requirements*

Design Verification testing included assessment of device dimensions, stent deployment and tensile testing of the applicable joints. The AXIOS Stent with Electrocautery Enhanced Delivery System was tested for design validation attributes. AXIOS Systems were evaluated in an *ex vivo* simulated use model for performance to the product specification. Based on the results of the bench performance testing, the modified Electrocautery Enhanced Delivery Systems meets the product design specification and performance requirements for its proposed intended use.

The AXIOS Stent with Electrocautery Enhanced Delivery System was evaluated in an Ex-Vivo Tissue Model to measure the comparative thermal effects of the AXIOS Electrocautery Enhanced Delivery System (11F) vs. the 10F Cook Cystotome on porcine tissue. In all tissue samples, the Electrocautery Enhanced Delivery System caused statistically significant less thermal damage to the tissue as compared to the Cystotome.

2. <u>Biocompatibility</u>

To verify the biocompatibility of the AXIOS Stent with Electrocautery Enhanced Delivery System the Company conducted biocompatibility testing pursuant to ISO 10993-1:2009 and FDA's Draft Guidance Document *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (2013)"*. Biocompatibility testing was conducted in accordance with the GLP regulations (21 CFR, Part 58).

The Electrocautery Enhanced Delivery System (Hot AXIOS Delivery System) is an "external communicating device" in contact with tissue for limited duration (≤24 hour) during pseudocyst access and stent implant procedures. Based on these characteristics, the following biocompatibility tests were performed: Cytotoxicity – ISO MEM Elution Method, L-929 Cells, Sensitization - ISO Guinea Pig Maximization Study, Irritation - ISO Intracutaneous Reactivity in Rabbits and Systemic (Acute) Toxicity - ISO Systemic Toxicity in Mice. There have been no changes to the AXIOS Stent design or materials; it is identical to the AXIOS Stent cleared in 510(k)s K123250 and K140561, therefore no new biocompatibility testing is warranted. Based on the test results, the Electrocautery Enhanced Delivery System is

biocompatible for the intended use.

3. Electromagnetic Compatibility and Electrical Safety

The AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS Device) was evaluated by Intertek NA, for conformance to the IEC 60601 family of standards. All completed testing passed the acceptance criteria as outlined in IEC 60601-1, 60601-1-6, 60601-2-2, 60601- 2-18, and ISO 14971 and as specified in the Final Study Reports provided by Intertek NA, Inc.

4. Animal

The safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System (Hot AXIOS) during transmural endoscopic access and drainage of a simulated pancreatic pseudocyst and the biliary tract was evaluated. The study evaluated the safety and performance of the AXIOS Stent with Electrocautery Enhanced Delivery System when performing a simulated endoscopic drainage procedure in a porcine model using the 06x08mm and 20x10mm stent models.

Cautery access and stent deployment using the AXIOS Stent with Electrocautery Enhanced Delivery System were compared to standard techniques as represented by access with the commercially available Cystotome (Cook Medical, Limerick Ireland) and the placement of an 20x10mm Stent with Electrocautery Enhanced Delivery System (the Electrocautery Enhanced Delivery System was not energized). A direct comparison of tissue heat affects and healing were evaluated post cautery access and AXIOS Stent placement. Effectiveness of the Electrocautery Enhanced Delivery System to access the target anatomy and deliver the AXIOS stent (device performance) was also assessed.

The study animals were survived for one (1) month after stent implantation followed by stent removal. Study animals were survived another 7 days after stent removal for histopathological evaluation. Histological evaluation of the heat affects and healing of the implant site was performed.

Access using cautery was successfully achieved and stents were successfully deployed in all animals. None of the stents migrated from the original position and all stents remained patent during the implant period (1 month). The tissue surrounding the stent implant sites was healthy in all animals. The gross and histological evaluation of the tissues treated with either the control (AXIOS without cautery) or test device (AXIOS with Electrocautery Enhanced Delivery System) showed excellent healing between the two luminal structures (bile duct or jejunum and stomach). Thermal heat effects were not apparent grossly or histologically within the tissues evaluated in the AXIOS Electrocautery Enhanced Delivery System treated animals.

V. Summary of Clinical Tests Performed:

A prospective multi-center, single-arm clinical study was conducted to demonstrate the safety and effectiveness of the AXIOS Stent with Electrocautery Enhanced Delivery System for

endoscopic transenteric drainage of pancreatic pseudocysts. The AXIOS Stent with Electrocautery Enhanced Delivery System is intended for the endoscopic ultrasonography (EUS) guided creation of an internal drainage conduit between the pancreatic pseudocyst and the stomach or duodenum. The AXIOS Electrocautery Enhanced Delivery System is designed to facilitate the creation of the access tract using electrosurgery while minimizing device exchanges for pseudocyst access. The design and manufacturing of AXIOS Stent remains unchanged.

Safety was evaluated as freedom from major complications with regard to stent placement and removal. Stent migration and tissue response for the period up to seven days after stent removal were also evaluated. Pseudocyst resolution and AXIOS device performance were evaluated to characterize effectiveness.

The study group consisted of symptomatic subjects who provided consent and were treated with the AXIOS Stent with Electrocautery Enhanced Delivery System.

Effectiveness: AXIOS Stents were placed in subjects with no intra-operative complications. AXIOS stent patency was confirmed with drainage visualized for all stents placed. In subjects treated PP, 100% of AXIOS devices remained in position at 30 or 60 days, and 81.1% of stent lumens remained patent at 30 days and 100% at 60 days. The AXIOS stent was successfully implanted in all study subjects (100%). Successful removal of the AXIOS stent was achieved in all subjects (100%) in which endoscopic removal PP was attempted. Overall clinical success was achieved in 83.3% of subjects.

Safety: Study results demonstrated that there were no unanticipated events related to the use of the device. Ninety percent (90%) of subjects were free from major complications. Ninety-three percent (93.3%) of subjects experienced no serious adverse events related to the device or index procedure. Serious adverse events deemed related to the AXIOS device or the index procedure was the same type of events as those generally associated with endoscopic pancreatic pseudocyst drainage with commercially available stents and delivery systems.

Conclusion:

The AXIOS Stent design and construction is optimized for controlled placement, maintaining patency, preventing migration and easy removal. Once placed, the stent provides a large diameter conduit and the bi-flange design secures access to the pseudocyst. The stent is provided fully covered to minimize tissue ingrowth.

The Electrocautery Enhanced Delivery System was used for access in 100% of patients and performed as intended in all cases. There were no adverse events or unanticipated adverse device effects attributed to electrocautery use.

The study of the AXIOS Stent with Electrocautery Enhanced Delivery System demonstrated the system to be predictable and easy to use. There were no intraoperative adverse events during AXIOS Stent placement and two during removal (both were minor bleeding not requiring transfusion). There were no unanticipated complications or new risks related to the

implantation and removal of the AXIOS Stent. The AXIOS Stent with Electrocautery Enhanced Delivery System is deployed using electrocautery in conjunction with current strategies and techniques for clinical assessment and treatment. In conclusion, the AXIOS Stent with Electrocautery Enhanced Delivery System is safe and effective for the endoscopic transenteric drainage of pancreatic pseudocysts.

VI. Substantial Equivalence:

Based on the results of the Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety and Animal testing, as well as clinical evaluations, the AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the currently cleared AXIOS Stent and Delivery System which was cleared by FDA in 510(k)s K123250 and K140561, and the Wilson-Cook Medical Cystotome cleared by FDA in 510(k) K022595. In regard to intended use/indication for use, technological characteristics, and principles of operation the modifications do not affect the performance or function of the device. The minor differences in the design between the modified and cleared devices do not raise any new types of safety or effectiveness questions as confirmed by non-clinical and clinical testing. Therefore, the AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the previously cleared predicate devices.

VII. Conclusions:

Boston Scientific concludes that based on the results of the Bench Performance, Biocompatibility, Electromagnetic Compatibility / Electrical Safety, Animal and Clinical Testing, that the modified AXIOS Stent with Electrocautery Enhanced Delivery System is substantially equivalent to the predicate devices.