



Food and Drug Administration  
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December 11, 2015

Boston Scientific Corporation  
Ashley Santos  
Regulatory Affairs Manager  
100 Boston Scientific Way  
Marlborough, MA 01752

Re: K153088  
Trade/Device Name: AXIOS Stent and Delivery System and AXIOS Stent and  
Electro-cautery 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: October 21, 2015  
Received: October 26, 2015

Dear Ashley Santos,

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,

**Benjamin R. Fisher -S**

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

## Indications for Use

510(k) Number (if known)

Unknown K153088

Device Name

AXIOS Stent and Delivery System and AXIOS Stent and Electro-cautery 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  $\geq 6$ cm in size, and symptomatic Walled Off Necrosis  $\geq 6$ cm in size, with  $\geq 70\%$  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.

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**SECTION 5**  
**510(k) SUMMARY**

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**510(k) SUMMARY**

**1. SUBMITTER:**

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Date Prepared: December 8, 2015

**2. DEVICE:**

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

Name of Device: AXIOS Stent and Electrocautery Enhanced Delivery System  
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

### 3. PREDICATE DEVICE:

Name of Device: AXIOS Stent and Delivery System  
510(k) Number: K152572  
Common Name: Pancreatic drainage stent and delivery system  
Classification Name: Pancreatic drainage stent and accessories  
Regulation Number: 21 CFR 876.5015  
Product Code: PCU  
Classification: Class II

Name of Device: AXIOS Stent and Electro-cautery Enhanced Delivery System  
510(k) Number: K150692  
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:

The main features of the AXIOS Stent and Delivery System and the AXIOS Stent and Electro-cautery Enhanced Delivery System are discussed below and presented in Table 5 - 1 . There have been no changes to the AXIOS Stent or the delivery systems; it is identical to the stent and delivery systems cleared in 510(k) K152572 and K150692.

#### AXIOS Stent:

The AXIOS Stent and Delivery System is designed to secure the apposition of tissue, minimize stent displacement and create a large access/drainage lumen.

#### AXIOS Non-Cautery 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.

#### AXIOS Electro-Cautery Enhanced Delivery System:

The stent is preloaded onto the AXIOS delivery catheter. The Electro-cautery Enhanced Delivery System consists of a catheter and an integrated handle with manual controls for positioning and deploying the AXIOS stent. The Electro-cautery Enhanced 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.

The Electro-cautery 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 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 use 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.

**Table 5-1: AXIOS Stent and Delivery System - Main Features**

<b>Component/Design</b>	<b>Feature Description</b>
<b>Catheter</b>	<ul style="list-style-type: none"> <li>• Provided sterile, for single-patient use</li> <li>• Working Length: <ul style="list-style-type: none"> <li>➢ 139cm Non-cautery Delivery System</li> <li>➢ 138cm Electro-cautery Enhanced Delivery System</li> </ul> </li> <li>• Outer Diameter 10.8 Fr</li> <li>• Fluoroscopy: AXIOS stent is contained between two (2)</li> </ul>
<b>Handle</b>	<ul style="list-style-type: none"> <li>• Staged delivery system for precise stent placement <ul style="list-style-type: none"> <li>⇒ Two (2)-step release of each flange, including a full "stop"</li> <li>⇒ Lock-out after the release of the first flange, preventing unintended deployment of the second flange</li> </ul> </li> </ul>
<b>Guidewire Compatibility</b>	0.035” insulated guidewires
<b>Endoscope Compatibility</b>	<ul style="list-style-type: none"> <li>• Compatible with 3.7 mm diameter or larger working channel</li> <li>• Delivery system is luer-locked to the proximal end of the biopsy port of the endoscope</li> </ul>
<b>AXIOS Stent</b>	
<b>AXIOS Stent Design</b>	<ul style="list-style-type: none"> <li>• Bi-flange or double anchor for Staged and Precise positioning</li> <li>• Flange/anchor designed to: <ul style="list-style-type: none"> <li>⇒ hold tissue layers in apposition</li> <li>⇒ prevent migration</li> </ul> </li> <li>• MR conditional</li> <li>• Provided sterile, for single-patient use</li> </ul>
<b>AXIOS Stent Lumen</b>	<ul style="list-style-type: none"> <li>• Large stent lumen diameter and short flow path/conduit to <ul style="list-style-type: none"> <li>⇒ Facilitate passive efficient drainage</li> <li>⇒ Facilitate passage of endoscopic tools for assessment and treatment</li> </ul> </li> </ul>
<b>AXIOS Stent Material</b>	<ul style="list-style-type: none"> <li>• Nitinol (Nickel-Titanium) <ul style="list-style-type: none"> <li>⇒ Shape memory and superelasticity for controlled placement and optimal deployment</li> <li>⇒ Corrosion resistant and biocompatible</li> </ul> </li> </ul>
<b>AXIOS Stent Covering</b>	<ul style="list-style-type: none"> <li>• Fully covered with Silicone <ul style="list-style-type: none"> <li>⇒ Well tolerated by surrounding tissue to minimize tissue ingrowth</li> <li>⇒ Provides leak protection and minimizes tissue ingrowth allowing for atraumatic stent removal</li> </ul> </li> </ul>

<p><b>AXIOS Stent Visualization</b></p>	<ul style="list-style-type: none"> <li>• The Stent is delivered constrained within a delivery system and deployed under visualization               <ul style="list-style-type: none"> <li>⇒ EUS confirmation of first flange deployment</li> <li>⇒ Direct endoscopic or EUS viewing of second flange deployment</li> <li>⇒ Radiopacity of Nitinol allows fluoroscopy of deployed stent</li> </ul> </li> </ul>
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**5. INDICATIONS FOR USE:**

The AXIOS Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts  $\geq 6$ cm in size, and symptomatic Walled Off Necrosis  $\geq 6$ cm in size, with  $\geq 70\%$  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. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:**

There are no differences in the technological characteristics between the proposed device and the predicate AXIOS Stent with Delivery System (K152572) and AXIOS Stent with Electro-cautery Enhanced Delivery System (K150692). The purpose of this Traditional 510(k) is to request clarification to the AXIOS indication for use. The physical device will remain unchanged from the predicates K152572 and K150692, but the revision to the indication requires a change to the product labeling. All other design specifications remain unchanged. Tables 5-2 and 5-3 include a technological comparison of the proposed device against the predicate device.

Characteristic	Subject Device AXIOS Stent and Delivery System	Primary Predicate AXIOS Stent and Delivery System K152572
Intended Use / Indications for Use	The AXIOS Stent is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts $\geq 6$ cm in size, and symptomatic Walled Off Necrosis $\geq 6$ cm in size, with $\geq 70\%$ 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.	To facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts $\geq 6$ cm in size, with $\geq 70\%$ 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.
Outer Catheter Length	139 cm	Same
Outer Catheter Shaft	10.8 Fr	Same

Inner Catheter Sheath	9 Fr with preloaded Stent	Same
Guidewire	0.035”	Same
Endoscope	Compatible with 3.7 mm	Same
Placement Site	Transgastric or transduodenal wall and into a pancreatic pseudocyst or Walled Off Necrosis	Transgastric or transduodenal wall and into a pancreatic pseudocyst
Pseudocyst/Walled	≥ 6cm in size	Same
Mode of Access or Operation	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.	Same
Stent Deployment Mechanism	Deployed via handle controls. Distal stent flange first followed by the proximal flange.	Same
Sterilization	Ethylene Oxide (EO)	Ethylene Oxide (EO)

**Table 5-3: AXIOS Stent with Electro-cautery Enhanced Delivery System Technological Comparison Table**

<b>Characteristic</b>	<b>Subject Device AXIOS Stent with Electro-cautery Enhanced Delivery System</b>	<b>Primary Predicate Device AXIOS Stent with Electro-cautery Enhanced Delivery System(K150692)</b>
Intended Use / 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.	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.
Outer Catheter Length	138 cm	Same
Outer Catheter Shaft	10.8 Fr	Same
Guidewire	0.035”	Same
Endoscope	Compatible with 3.7 mm	Same
Placement Site	Transgastric or transduodenal wall and into a pancreatic pseudocyst or Walled Off Necrosis	Transgastric or transduodenal wall and into a pancreatic pseudocyst
Pseudocyst/Walled	≥ 6cm in size	Same

Mode of Access or Operation	Electrosurgically punctures hole at the placement site. After access, deploy the AXIOS Stent using a two stage process. Distal stent flange first followed by the proximal flange.	Same
Stent Deployment Mechanism	Deployed via handle controls. Distal stent flange first followed by the proximal flange.	Same
Cutting Current	80-120 Watts	Same
Sterilization	Ethylene Oxide (EO)	Same

**7. PERFORMANCE DATA:**

**Non-Clinical Testing:**

No performance data was required for this submission.

**Clinical Data:**

The published clinical guidelines identified in the “Classification of acute pancreatitis- 2012: revision of the Atlanta classification and definitions by international consensus”<sup>1</sup>, was the basis for requesting the revision to the indication for use. BSC is requesting to clarify the AXIOS indication for use to align with the “fluid collection” classifications identified in this clinical article. The safety and effectiveness of the AXIOS stent when used for drainage of encapsulated pancreatic collections  $\geq 6$ cm in size, with  $\geq 70\%$  fluid content/  $< 30\%$  necrotic material that are adherent to the gastric or bowel wall, which includes symptomatic pancreatic pseudocysts and symptomatic Walled Off Necrosis has been established via IDEs G110068 and G130266. Therefore, no additional clinical data is required to support the revision to this indication for use statement.

**8. CONCLUSION:**

The revised indication for use that Boston Scientific Corporation is requesting for the proposed AXIOS Stent with Delivery System and AXIOS Stent with Electro-cautery Enhanced Delivery System is to align with the “fluid collection” definitions identified in the “Classification of acute pancreatitis- 2012: revision of the Atlanta classification and definitions by international consensus”. The revised indication for use does not raise new questions of safety and effectiveness. The safety and effectiveness of the proposed AXIOS Stent with Delivery System and AXIOS Stent with Electro-cautery Enhanced Delivery System has been established.

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<sup>1</sup> Banks, Peter A., “Classification of acute pancreatitis- 2012: revision of the Atlanta classification and definitions by international consensus” published in Gut 2013, Volume 62, pgs. 102-111.