



Food and Drug Administration
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October 6, 2015

Boston Scientific Corporation
Ashley Santos
Regulatory Affairs Manager
453 Ravendale Drive, Suite H
Mountain View, CA 94043

Re: K152572
Trade/Device Name: AXIOS Stent and Delivery System
Regulation Number: 21 CFR§ 876.5015
Regulation Name: Pancreatic drainage stent and delivery system
Regulatory Class: II
Product Code: PCU
Dated: September 4, 2015
Received: September 9, 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

STATEMENT OF INDICATIONS FOR USE

510(k) NUMBER (IF KNOWN): K152572

DEVICE NAME: AXIOS Stent and Delivery System

INDICATIONS FOR USE:

The AXIOS Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, with $\geq 70\%$ fluid content that are adherent to the bowel wall. Once placed, the AXIOS Stent functions as a 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.

Concurrence of CDRH, Office of Device Evaluations (ODE)

Prescription Use X
(Per 21 CFR 901.109)

OR

Over-The-Counter Use _____

510(k) SUMMARY
AXIOS Stent and Delivery System

Date Prepared: October 2, 2015

Manufacturer: Boston Scientific Corporation
453 Ravendale Drive, Suite H
Mountain View, CA 94043

Contact: Ashley Santos
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Regulatory Affairs Manager (Marlborough, MA)
Phone: 508-683-4359
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Trade Name: AXIOS Stent and Delivery System

Common Name: Pancreatic Stent

Device Class: Class II

Regulation: 21 CFR 876.5015

Product Code: PCU

Review Panel: Reproductive, Gastro-Renal and Urological Devices

Predicate Device Information:

Manufacturer	Name of Predicate Device	510(k) #	Clearance Date
Boston Scientific*	AXIOS Stent and Delivery System	K140561	April 23, 2014
Boston Scientific*	AXIOS Stent with Electrocautery Enhanced Delivery System	K150692	August 8, 2015

*Manufacturer is now Boston Scientific Corporation through acquisition of Xlumena in April 2015.

Description:

The AXIOS Stent and Delivery System is designed to secure the apposition of tissue, minimize stent displacement and create a large access/drainage lumen. The main features of the AXIOS Stent and Delivery System are presented in **Table 2-1**. There have been no changes to the AXIOS Stent or the delivery system; it is identical to the stent and delivery system cleared in 510(k) K140561.

Table 2-1: AXIOS Stent and Delivery System - Main Features

Component/Design	Feature Description
Catheter	<ul style="list-style-type: none"> • Provided sterile, for single-patient use • Working Length: 138 cm • Outer Diameter 10.8 Fr • Fluoroscopy: AXIOS stent is contained between two (2) Platinum Iridium markers
Handle	<ul style="list-style-type: none"> • Staged delivery system for precise stent placement <ul style="list-style-type: none"> ⇒ 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	<ul style="list-style-type: none"> • 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	
AXIOS Stent Design	<ul style="list-style-type: none"> • Bi-flange or double anchor for Staged and Precise positioning • Flange/anchor designed to: <ul style="list-style-type: none"> ⇒ hold tissue layers in apposition ⇒ prevent migration • MR conditional • Provided sterile, for single-patient use
AXIOS Stent Lumen	<ul style="list-style-type: none"> • Large stent lumen diameter and short flow path/conduit to <ul style="list-style-type: none"> ⇒ Facilitate passive efficient drainage ⇒ Facilitate passage of endoscopic tools for assessment and treatment
AXIOS Stent Material	<ul style="list-style-type: none"> • Nitinol (Nickel-Titanium) <ul style="list-style-type: none"> ⇒ Shape memory and superelasticity for controlled placement and optimal deployment ⇒ Corrosion resistant and biocompatible
AXIOS Stent Covering	<ul style="list-style-type: none"> • Fully covered with Silicone <ul style="list-style-type: none"> ⇒ Well tolerated by surrounding tissue to minimize tissue ingrowth ⇒ Provides leak protection and minimizes tissue ingrowth allowing for atraumatic stent removal
AXIOS Stent Visualization	<ul style="list-style-type: none"> • The Stent is delivered constrained within a delivery system and deployed under visualization <ul style="list-style-type: none"> ⇒ EUS confirmation of first flange deployment ⇒ Direct endoscopic or EUS viewing of second flange deployment ⇒ Radiopacity of Nitinol allows fluoroscopy of deployed stent

The AXIOS Stent and Delivery System is provided sterile, disposable and intended for single patient use. 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.

Device Modification:

The AXIOS Stent with Delivery System Directions for Use (DFU) is being modified to align with the DFU of the AXIOS Stent with Electrocautery Delivery System that was cleared per K150692. The DFU modification involves changes to the Magnetic Resonance (MR) information, clinical information, and procedural instructions. These changes are supported by the MR test data and clinical information that was submitted and cleared per K150692. The patient implant card is also being revised to align with the AXIOS Stent with Electrocautery Delivery System language that was cleared per K150692.

Indications for Use:

Identical to the cleared AXIOS Stent and Delivery System (K140561) and the AXIOS Stent with Electrocautery Delivery System (K150692):

The AXIOS Stent and Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, with $\geq 70\%$ fluid content that are adherent to the bowel wall. Once placed, the AXIOS Stent functions as a 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.

Substantial Equivalence Comparison:

There are no changes to the device in any way. The intended use/indication for use, technological characteristics, and principles of operation are the same as the predicate device. The minor changes to the DFU do not raise any new types of safety or effectiveness questions as confirmed by MR testing and a clinical trial. Therefore, the AXIOS Stent and Delivery System is substantially equivalent to the previously cleared predicate devices.

Summary of Verification & Validation Activities:

No additional verification or validation activities were required to support the DFU changes proposed in this submission for the AXIOS Stent with Delivery System. The MR data and clinical data that supported the proposed labeling modifications were also used to support the same labeling changes that were cleared for the AXIOS with Electrocautery Enhanced Delivery System per K150692.

Conclusion:

The modified DFU of the AXIOS Stent and Delivery System is substantially equivalent to the predicate devices.