August 26, 2019

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

Re: K192043
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: Class II
Product Code: PCU, KNS
Dated: July 29, 2019
Received: July 31, 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -S

Daniel G. Walter, Jr.
Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

Device Name
AXIOS Stent and Electrocautery-Enhanced Delivery System

Indications for Use (Describe)
The AXIOS Stent and Electrocautery Enhanced Delivery System 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.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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FORM FDA 3881 (7/17)
SECTION 5. 510(K) SUMMARY

510(k) SUMMARY

1. Submitter:
   Boston Scientific Corporation
   100 Boston Scientific Way
   Marlborough, MA 01752

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

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: PCU/ KNS
   Classification: Class II

3. Predicate Device
   Trade Name: Axios™ Stent and Electrocautery-Enhanced Delivery System & AXIOS Stent and Delivery System
   510(k) Number: K181905
   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: PCU/ 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 Stent. 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**

<table>
<thead>
<tr>
<th>Component/Design</th>
<th>Feature Description</th>
</tr>
</thead>
</table>
| **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 | |
| 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 (15mm x 15mm) and Electrocautery Enhanced Delivery System is identical to the predicate AXIOS Stent (15mm x 10mm) and Electrocautery Enhanced Delivery System with the exception of the stent saddle length. The proposed AXIOS Stent has a stent saddle length of 15 mm. The intended use and mode of operation remains identical to the predicate AXIOS Stent and Electrocautery Enhanced Delivery system cleared via K181905. The Electrocautery Enhanced Delivery System is identical to the predicate AXIOS 15x10mm Electrocautery Enhanced Delivery System except for two minor modifications to the stent deployment hub and the stent mounting length.

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.

<table>
<thead>
<tr>
<th>#</th>
<th>Test</th>
<th>Results (Pass/ Fail)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Deployed Stent Saddle Length</td>
<td>Pass</td>
</tr>
<tr>
<td>2</td>
<td>Deployed Stent Saddle Outer Diameter</td>
<td>Pass</td>
</tr>
<tr>
<td>3</td>
<td>Deployed Stent Flange Width</td>
<td>Pass</td>
</tr>
<tr>
<td>4</td>
<td>Stent Pull-out Force (tensile)</td>
<td>Pass</td>
</tr>
<tr>
<td>5</td>
<td>Stent (Saddle) Radial Strength –in compression &amp; expansion</td>
<td>Pass</td>
</tr>
<tr>
<td>6</td>
<td>Deployment Force</td>
<td>Pass</td>
</tr>
<tr>
<td>7</td>
<td>Implant Anchor Function- Retention (tensile)</td>
<td>Pass</td>
</tr>
<tr>
<td>8</td>
<td>Magnetic Resonance Testing</td>
<td>Pass</td>
</tr>
</tbody>
</table>

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<td>Pass</td>
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<tr>
<td>7</td>
<td>Implant Anchor Function- Retention (tensile)</td>
<td>Pass</td>
</tr>
</tbody>
</table>

Conclusion

The information Boston Scientific Corporation provided in this submission demonstrates that the proposed AXIOS 15mm x 15mm Stent and Electrocautery Enhanced Delivery System is substantially equivalent to the currently cleared AXIOS 15mm x 10mm Stent and Electrocautery Enhanced Delivery System K181905.