August 18, 2023

Boston Scientific Corporation
Alexis Erazo
Principal Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Maryland 01752

Re: DEN230019
Trade/Device Name: AXIOS Stent and Electrocautery-Enhanced Delivery System (10 mm x 10 mm Stent); AXIOS Stent and Electrocautery-Enhanced Delivery System (15 mm x 10 mm Stent)
Regulation Number: 21 CFR 876.5016
Regulation Name: Gallbladder drainage stent and delivery system
Regulatory Class: Class II
Product Code: QXH
Dated: March 24, 2023
Received: March 27, 2023

Dear Alexis Erazo:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the AXIOS Stent and Electrocautery-Enhanced Delivery System (10 mm x 10 mm Stent); AXIOS Stent and Electrocautery-Enhanced Delivery System (15 mm x 10 mm Stent), a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The AXIOS Stent and Electrocautery Enhanced Delivery System is indicated for use to facilitate transgastric or transduodenal endoscopic drainage of the gallbladder in patients with acute cholecystitis who are at high risk for surgery.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the AXIOS Stent and Electrocautery-Enhanced Delivery System (10mm x 10mm Stent); AXIOS Stent and Electrocautery-Enhanced Delivery System (15 mm x 10 mm Stent), and substantially equivalent devices of this generic type, into Class II under the generic name gallbladder drainage stent and delivery system.

FDA identifies this generic type of device as:

> **Gallbladder drainage stent and delivery system.** A gallbladder drainage stent is a prescription device intended to facilitate transgastric or transduodenal endoscopic drainage of the gallbladder. This device may also include a delivery system.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On March 27, 2023, FDA received your De Novo requesting classification of the AXIOS Stent and Electrocautery-Enhanced Delivery System (10mm x 10mm Stent); AXIOS Stent and Electrocautery-Enhanced Delivery System (15mm x 10mm Stent). The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the AXIOS Stent and Electrocautery-Enhanced Delivery System (10mm x 10mm Stent); AXIOS Stent and Electrocautery-Enhanced Delivery System (15mm x 10mm Stent) into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request as well as material provided via interactive review, FDA has determined that, for the previously stated indications for use, the AXIOS Stent and Electrocautery-Enhanced Delivery System (10 mm x 10 mm Stent); AXIOS Stent and Electrocautery-Enhanced Delivery System (15 mm x 10 mm Stent) can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Procedural complications, leading to recurrent cholecystitis • Improper stent placement • Improper stent removal • Stent obstruction/ingrowth • Stent migration/dislodgement	Clinical performance data Non-clinical performance testing Labeling
Tissue unable to support stent placement due to: • Lack of gallbladder wall integrity • Lack of gallbladder adherence to bowel wall	Clinical performance data Non-clinical performance testing Labeling
Infection/sepsis	Sterilization validation Labeling
Adverse tissue reaction	Biocompatibility evaluation

MR incompatibility, leading to tissue damage	Non-clinical performance testing

In combination with the general controls of the FD&C Act, the gallbladder drainage stent and delivery system is subject to the following special controls:

(1) Clinical performance data must demonstrate that the device performs as intended under its anticipated conditions of use, and capture any adverse events observed during clinical use. Data must describe major clinical outcomes including stent patency, stent placement, and stent removal.

(2) Non-clinical performance testing must demonstrate that the stent and any associated delivery systems perform as intended under anticipated conditions of use. The following performance characteristics must be tested to demonstrate the stent will withstand forces and conditions encountered during use:
   (i) Deployment testing of the stent under simulated use conditions;
   (ii) Removal force testing to demonstrate that the stent will remain in place;
   (iii) Compression and expansion force testing;
   (iv) Dimensional verification testing;
   (v) Tensile testing of joints and materials;
   (vi) Fatigue testing to characterize material strength; and
   (vii) Corrosion testing.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of patient-contacting components of the device.

(5) Performance data must support the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the requested shelf life.

(6) Performance data must evaluate the compatibility of the stent in a magnetic resonance (MR) environment.

(7) Labeling must include:
   (i) Specific instructions and the expertise needed for the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device;
   (ii) A detailed summary of the clinical data pertinent to use of the device, including device- and procedure-related complications;
   (iii) A detailed summary of the device technical parameters; and
   (iv) An expiration date or shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the gallbladder drainage stent and delivery system they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Nicholas Clay, Ph.D., at Nicholas.clay@fda.hhs.gov.

Sincerely,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
OHT3: Office of GastroRenal, ObGyn,
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