DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 2, 2014

Jane Beggs
Vice President of Regulatory and Clinical Affairs
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Re: K123250
AXIOS Stent and Delivery System
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 876.5015
Regulation Name: Pancreatic drainage stent and delivery system
Regulatory Classification: Class II
Product Code: PCU
Dated: February 15, 2013
Received: February 19, 2013

Dear Ms. Beggs:

This letter corrects our classification order of December 18, 2013.

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 Delivery System, a prescription device under 21 CFR Part 801.109 that is indicated for use 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 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. FDA concludes that this device should be classified into class II. This order, therefore, classifies the AXIOS Stent and Delivery System, and substantially equivalent devices of this generic type, into class II under the generic name, Pancreatic drainage stent and delivery system.

FDA identifies this generic type of device as:

> **Pancreatic drainage stent and delivery system:** A pancreatic drainage stent is a prescription device that consists of a self-expanding, covered, metallic stent, intended for placement to facilitate transmural endoscopic drainage of pancreatic pseudocysts. This stent is intended to be removed upon confirmation of pseudocyst resolution. This device may also include a delivery system.

Section 513(f)(2) of 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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on February 1, 2013, automatically classifying the AXIOS Stent and Delivery System in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On February 19, 2013, FDA received your *de novo* requesting classification of the AXIOS Stent and Delivery System into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the AXIOS Stent and Delivery System 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, FDA has determined that the AXIOS Stent and Delivery System indicated for use to facilitate transgastric or transduodenal endoscopic drainage of symptomatic pancreatic pseudocysts ≥ 6 cm in size, with ≥ 70% fluid content that are adherent to the bowel wall can be classified in class II with the establishment of special controls for class II. Once placed, the AXIOS stent functions as a port allowing passage of standard and therapeutic endoscopes to facilitate debridement, irrigation and cystoscopy. The AXIOS stent is intended for implantation up to 60 days and should be removed upon confirmation of pseudocyst resolution. 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 with the device type are summarized in Table 1.

Table 1 - Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Adverse Tissue Reaction or Infection	Biocompatibility testing Sterility testing Labeling
Partial expansion of stent	Clinical experience In-vitro (bench) testing Labeling
Failure to deliver stent	Clinical experience In-vitro (bench) testing Labeling
Stent occlusion	Clinical experience

Identified Risk	Mitigation Measure
	Labeling
Stent ingrowth/failure to remove stent	Clinical experience Labeling
Stent migration (passive dislocation)	Clinical experience In-vitro (bench) testing Labeling
Stent dislodgement (active dislocation)	Clinical experience In-vitro (bench) testing Labeling
Tissue ulceration	Clinical experience In-vitro (bench) testing Labeling
Procedural complications	Clinical experience Labeling

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

1. The device and elements of the delivery device that may contact the patient must be demonstrated to be biocompatible.

2. Performance data must demonstrate the sterility of patient-contacting components of the device.

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

4. Non-clinical testing data must demonstrate that the stent and delivery system perform as intended under anticipated conditions of use. The following performance characteristics must be tested:

    a. Deployment testing of the stent and delivery system must be conducted under simulated use conditions.

    b. Removal force testing must be conducted. The removal force testing must demonstrate that the stent can be safely removed, and that the stent will remain in place when subjected to forces encountered during use.

    c. Expansion force testing must be conducted. The expansion force must demonstrate that the forces exerted by the stent will not damage the tissue surrounding the stent.

    d. Compression force testing must be conducted. The compression force must demonstrate that the stent will withstand the forces encountered during use.

e. Dimensional verification testing must be conducted.

f. Tensile testing of joints and materials must be conducted. The minimum acceptance criteria must be adequate for its intended use.

g. Fatigue testing must be conducted. Material strength must demonstrate that the stent will withstand forces encountered during use.

h. Corrosion testing must be conducted. Corrosion resistance must demonstrate that the stent will withstand conditions encountered during use.

5. Non-clinical testing must evaluate the compatibility of the stent in a magnetic resonance (MR) environment.

6. Well-documented clinical experience must demonstrate safe and effective use, and capture any adverse events observed during clinical use.

7. Labeling must include the following:

   a. Appropriate instructions, warnings, cautions, limitations, and information related to the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.

   b. A warning that the safety and patency of the stent has not been established beyond the duration of the documented clinical experience.

   c. Specific instructions and the qualifications and clinical training needed for the safe use of the device, including deployment of the device, maintenance of the drainage lumen, and removal of the device.

   d. Information on the patient population for which the device has been demonstrated to be effective.

   e. A detailed summary of the clinical experience pertinent to use of the device.

   f. A detailed summary of the device technical parameters.

   g. A detailed summary of the device- and procedure-related complications pertinent to use of the device.

   h. An expiration date/shelf life.

In addition, this is a prescription device and must comply with 21 CFR 801.109. 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 *pancreatic drainage stent and delivery system* they intend to market prior to marketing the device and receive clearance to market from FDA.

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 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.

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.

If you have any questions concerning this classification order, please contact Jeffrey Cooper at 301-796-6517.

Sincerely yours,

Jonette R. Foy -S

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