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

June 3, 2016

Boston Scientific Corporation
Mr. Thomas Hirte
Senior Manager, Regulatory Affairs, Endoscopy
100 Boston Scientific Way
Marlborough, MA 01752

Re: DEN150040
WallFlex Biliary RX Fully Covered Stent System RMV
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 21 CFR 876.5011
Regulation Name: Metallic Biliary Stent System for Benign Strictures
Regulatory Classification: Class II
Product Code: PNB
Dated: August 27, 2015
Received: August 28, 2015

Dear Mr. Hirte:

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 WallFlex Biliary RX Fully Covered Stent System RMV, a prescription device under 21 CFR Part 801.109 that is *indicated for indwell up to 12 months in the treatment of benign biliary strictures secondary to chronic pancreatitis*. FDA concludes that this device should be classified into class II. This order, therefore, classifies the WallFlex Biliary RX Fully Covered Stent System RMV, and substantially equivalent devices of this generic type, into class II under the generic name, Metallic Biliary Stent System for Benign Strictures.

FDA identifies this generic type of device as:

> **Metallic Biliary Stent System for Benign Strictures:** A metallic biliary stent system for benign strictures is a prescription device intended for the treatment of benign biliary strictures. The biliary stents are intended to be left indwelling for a limited amount of time and subsequently removed. The device consists of a metallic stent and a delivery system intended to place the stent in the bile duct. This device type is not intended for use in the vasculature.

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 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.

On August 28, 2015, FDA received your *de novo* requesting classification of the WallFlex Biliary RX Fully Covered Stent System RMV into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the WallFlex Biliary RX Fully Covered Stent System RMV 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 and during interactive review, FDA has determined that the WallFlex Biliary RX Fully Covered Stent System RMV, *indicated for indwell up to 12 months in the treatment of benign biliary strictures secondary to chronic pancreatitis,* 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 Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk	**Mitigation Measure**
Adverse tissue reaction	Biocompatibility Evaluation Labeling
Infection	Sterilization Validation Shelf Life Validation Labeling
Bile duct obstruction • Stent migration • Stent does not resolve obstruction • Stent cannot be placed • Expansion/compression forces • Foreshortening	Clinical Performance Testing Non-clinical Performance Testing Shelf Life Validation Labeling
Trauma to bile ducts • During stent deployment • During removal • Due to stent migration • During stent indwell • Inability to safely remove stent • Expansion/compression forces	Clinical Performance Testing Non-clinical Performance Testing Shelf Life Validation Labeling

In combination with the general controls of the FD&C Act, the Metallic Biliary Stent System for Benign Strictures is subject to the following special controls:

1. Clinical performance testing must demonstrate or provide the following:
   a. The ability to safely place and subsequently remove the stent after the maximum labeled indwell period
   b. All adverse event data including bile duct obstruction and trauma to the bile duct
   c. The stent resolves strictures during the maximum labeled indwell period
   d. Stricture resolution is maintained post-stent removal
2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be demonstrated:
   a. Corrosion testing to demonstrate that the stent maintains its integrity during indwell and does not release potentially toxic levels of leachables.
   b. Stent dimensional testing supports the intended use.
   c. Compression and expansion forces must be characterized.
   d. The delivery catheter must deliver the stent to the intended location and the stent must not be adversely impacted by the delivery catheter during deployment and catheter withdrawal.
   e. The delivery system must withstand clinically anticipated forces.
   f. Compatibility in a magnetic resonance environment.
3. All patient contacting components of the device must be demonstrated to be biocompatible.
4. Performance data must demonstrate the sterility of the device components intended to be provided sterile.
5. Shelf-life testing must demonstrate that the device maintains its performance characteristics and that packaging maintains sterility for the duration of the labeled shelf-life.
6. Labeling for the device must include:
   a. A detailed summary of the clinical testing including device effectiveness, and device- and procedure-related adverse events
   b. Appropriate warning(s) to accurately ensure usage of the device for the intended patient population
   c. Shelf life
   d. Compatibility information for use in the magnetic resonance environment
   e. Stent foreshortening information supported by dimensional testing

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 Metallic Biliary Stent System for Benign Strictures 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 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); 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 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.

If you have any questions concerning this classification order, please contact April Marrone, Ph.D. at (240) 402-6510.

Sincerely,

Jonette R. Foy -S

Jonette Foy, Ph.D.
Deputy Director
for Engineering and Science Review
Office of Device Evaluation
Center for Devices and Radiological Health