September 21, 2018

Boston Scientific Corporation
Kayla Mackey
Regulatory Affairs Specialist II
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K180144
Trade/Device Name: Agile Esophageal Stent System
Regulation Number: 21 CFR 878.3610
Regulation Name: Esophageal Prosthesis
Regulatory Class: Class II
Product Code: ESW
Dated: August 22, 2018
Received: August 23, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jeffrey W. Cooper -S
2018.09.21 15:47:15
-04'00'

for
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
~~Unknown~~ K180144

Device Name
Agile Esophageal Stent System

Indications for Use *(Describe)*
The Agile Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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SECTION 5: 510(K) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Kayla Mackey
Regulatory Affairs Specialist II
Telephone: 508-683-4534
Fax: 508-683-5939

Date Prepared: January 16, 2018

2. Device:

Trade Name:	Agile™ Esophageal Stent System
Classification Name:	Esophageal Prosthesis
Regulation Number:	21 CFR 878.3610
Product Code:	ESW
Classification:	Class II

3. Predicate Device(s):

Trade Name:	Wallflex Esophageal Fully & Partially Covered Stent System
510(k) Number:	K091510/ K073266
Classification Name:	Esophageal Prosthesis
Regulation Number:	21 CFR 878.3610
Product Code:	ESW
Classification:	Class II

Trade Name:	Taewoong Niti-S Esophageal TTS Stent
510(k) Number:	K123205
Classification Name:	Esophageal Prosthesis
Regulation Number:	21 CFR 878.3610
Product Code:	ESW
Classification:	Class II

Trade Name:	Merit Alimaxx-ES Esophageal Stent
510(k) Number:	K080838

Classification Name: Esophageal Prosthesis
Regulation Number: 21 CFR 878.3610
Product Code: ESW
Classification: Class II

Reference Device:

Trade Name: Ultraflex Esophageal NG Stent System
510(k) Number: K091816
Classification Name: Esophageal Prosthesis
Regulation Number: 21 CFR 878.3610
Product Code: ESW
Classification: Class II

4. Device Description:

The Agile™ Esophageal Stent System is intended for the endoscopic placement of the self-expanding nitinol stent for maintaining luminal patency in esophageal strictures. The flexible Agile Stent and through-the scope Delivery System allow for stent placement through direct visualization. The Agile™ Esophageal Stent System is supplied sterile.

The Agile™ Stent is a flexible, MR conditional, self-expanding, braided nitinol stent. The proximal and distal ends of the stent have a flare which is larger in diameter than the stent body. The stent wires at each end of the flare are looped. A suture is threaded within the looped ends of both the proximal and distal stent flares to aid in repositioning during initial placement. The proposed Agile Stent is both fully and partially covered in a silicone covering.

The Agile™ Stent comes preloaded and constrained in the delivery system. The delivery system consists of two coaxial shafts compatible with a minimum 3.7mm working channel of a therapeutic gastroscope. The exterior tube is used to constrain the stent before deployment and to reconstrain the stent after partial deployment. The delivery system has radiopaque and visual markers to aid the user in accurate stent placement. There are three visual markers on the delivery system handle to aid in the placement of the stent under endoscopic visualization and four radiopaque markers on the interior of the delivery system to aid in placement of the stent under fluoroscopic visualization.

Proposed Model Configurations:

Table 5-1: Agile Partially Covered Stent Sizes

UPN	Stent Size		
	Stent Diameter	Stent Length	Flare Diameter
M00517200	14mm	62 mm	19mm
M00517210	14mm	102 mm	19mm
M00517220	14mm	119 mm	19mm
M00517230	14mm	148 mm	19mm
M00517240	18mm	59 mm	23mm
M00517250	18mm	97 mm	23mm
M00517260	18mm	119 mm	23mm
M00517270	18mm	149 mm	23mm

Table 5-1: Agile Partially Covered Stent Sizes			
UPN	Stent Size		
	Stent Diameter	Stent Length	Flare Diameter
M00517280	23mm	62 mm	28mm
M00517290	23mm	101 mm	28mm
M00517300	23mm	120 mm	28mm
M00517310	23mm	150 mm	28mm

Table 5-2: Agile Fully Covered Stent Sizes			
UPN	Stent Size		
	Stent Diameter	Stent Length	Flare Diameter
M00517400	14mm	62 mm	19mm
M00517410	14mm	102 mm	19mm
M00517420	14mm	119 mm	19mm
M00517430	14mm	148 mm	19mm
M00517440	18mm	59 mm	23mm
M00517450	18mm	97 mm	23mm
M00517460	18mm	119 mm	23mm
M00517470	18mm	149 mm	23mm
M00517480	23mm	62 mm	28mm
M00517490	23mm	101 mm	28mm
M00517500	23mm	120mm	28mm
M00517510	23mm	150mm	28mm

5. Indications for Use:

The Agile™ Esophageal Stent System is intended for maintaining esophageal luminal patency in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors, and occlusion of concurrent esophageal fistulas.

6. Technological Characteristics

The intended use of the proposed Agile™ Esophageal Stent System is identical to the predicate Wallflex Esophageal Fully and Partially Covered Stent System, Taewoong Niti-S TTS Esophageal Stent, and Merit Alimaxx-ES Esophageal Stent.

The proposed Agile™ Esophageal Stent Delivery system is similiar to the predicate Taewoong Niti-S TTS Esophageal delivery system in overall length and working length, outer diameter, method of placement, and guidewire compatibility.

The proposed Agile™ Esophageal Stent is similar to the predicate Wallflex Esophageal Fully and Partially Covered Stents, Taewoong Niti-S TTS Esophageal Stents, and Merit Alimaxx-ES Esophageal Stents in terms of performance, stent diameter, flare diameter, and stent length. The

stent materials are similar between the proposed Agile Esophageal Stent System and the predicate Wallflex Esophageal Fully and Partially Covered Stents.

7. Biocompatibility Analysis

The following biocompatibility tests have been completed for the proposed Agile Esophageal Fully Covered Stent System.

Table 5-3 Summary of Agile Esophageal Fully Covered Stent Biocompatibility Testing	
Test	Results
MEM Elution Cytotoxicity/Part 5	Pass
Sub-acute (Subchronic)/Part 11/ Intravenous Toxicity	Pass
Guinea Pig Maximization Sensitization/Part 10	Pass
Intracutaneous Reactivity/Part 10	Pass
Sub-acute (Subchronic)/Part 11/ Intraperitoneal Toxicity	Pass
Materials Mediated Rabbit Pyrogen/Part 11	Pass
Ames Mutagenicity/ Part 3	Pass
Acute Systemic Injection/Part 11	Pass
Mouse Lymphoma / Part 3	Pass
Analytical Testing/ Part 18 (NVR; GCMS; LC-MS; ICPMS; HS-GC-MS)	Pass
Implantation (Intramuscular)/ Part 6 (4weeks)	Pass
Implantation (Intramuscular)/ Part 6 (13 weeks)	Pass

Table 5-4 Summary of Agile Esophageal Delivery System Biocompatibility Testing	
Test	Results
MEM Elution Cytotoxicity/Part 5	Pass
Intracutaneous Reactivity/Part 10	Pass
Guinea Pig Maximization Sensitization/Part 10	Pass
Analytical testing	Pass

Ultraflex Esophageal NG Stent System (K091816) was used as a reference device to support the biocompatibility of the Agile Esophageal Partially Covered Stent. The following biocompatibility tests have been leveraged from Ultraflex Esophgeal NG Stent System (K091816).

Table 5-5 Summary of Ultraflex Esophageal NG Stent System Biocompatibility Testing	
Test	**Results**
Cytotoxicity	Pass
Sensitization	Pass
Intracutaneous Reactivity	Pass
Systemic Toxicity- Acute Systemic Toxicity	Pass
Subacute Toxicity- Intravenous	Pass
Subacute Toxicity- Intraperitoneal	Pass
Genotoxicity- Ames Assay	Pass
Mouse Lymphoma	Pass
Mouse Lymphoma / Part 3	Pass
Implantation (12 weeks)	Pass
USP Physiochemical	Pass

8. Performance Data

The proposed Agile™ Esophageal Stent System successfully passed all pre-defined product specifications for the tests performed. Below is a summary of the tests performed on the Agile Esophageal Stent System:

Table 5-6 Summary of Bench Tests and Results		
No.	**Test**	**Results (Pass/Fail)**
1	Guidewire Passage	Pass
2	Trackability/Pushability	Pass
3	Deployment and Reconstrainment	Pass
4	Delivery System Removal	Pass
5	Immediate Stent Opening	Pass
6	Delivery System Withdrawal	Pass
7	Stent Hoop Expansion and Compression Force	Pass
8	Delivery System Working Length	Pass
9	Delivery System Outer Diameter	Pass
10	Visual Transition Zone Length	Pass
11	Stent Foreshortening	Pass
12	Final Unconstrained Stent Length	Pass
13	Stent Flare Length	Pass

14	Non-Covered Length (Partially Covered Codes Only)	Pass
15	Stent Covering Length (Partially Covered Codes Only)	Pass
16	Stent Diameter	Pass
17	Flare Diameter	Pass
18	Tip to Inner Member Bond Tensile	Pass
19	Inner Jacket to Handle Assembly Tensile	Pass
20	Reconstrainment Band to Inner Jacket Tensile	Pass
21	Exterior Tube to Handle Bond Tensile	Pass
22	Inner Jacket to Inner Member Bond Tensile	Pass
23	Exterior Tube Transition Zone Tensile	Pass
24	Suture Pull Strength Test	Pass
25	Corrosion Testing	Pass
26	Fatigue Testing	Pass
27	Deployment Accuracy	Pass
28	Magnetic Resonance Testing	Pass

Table 5-7 Summary of the Comparative Bench Tests	
No.	**Test**
29	Stent Hoop Expansion & Compression Force

9. Comparative Bench Testing

Comparative bench testing was conducted on the Agile Esophageal Stent System and its substantially equivalent predicate device. The comparative testing demonstrated that the Stent Hoop Expansion and Compression Force of the Agile Esophageal Stents falls within the range of the currently marketed predicates for the propose stent diameters.

Conclusion:

The information Boston Scientific provided in this submission demonstrates that the proposed Agile Esophageal Stent System is substantially equivalent to the currently cleared predicate devices thru the design and performance characteristics and indication for use.