January 2, 2020

Boston Scientific Corporation
Jois Zuniga-Gamboa
Peripherical Interventional Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, MN 55311

Re: K191446
Trade/Device Name: Flexima™ Biliary Catheter System
Flexima™ Biliary Catheter System Kit
Flexima™ Biliary Catheter System with Radiopaque Marker
Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip
Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip and Radiopaque Marker.
Flexima™ Ureteral Stent System and Flexima™ Ureteral Stent System Kit
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD, FGE
Dated: November 26, 2019
Received: December 4, 2019

Dear Jois Zuniga-Gamboa:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the

enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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,

Jessica K. Nguyen, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K191446

Device Name
Flexima™ Ureteral Stent System and Flexima™ Ureteral Stent System Kit. Flexima™ Biliary Catheter System / Flexima™ Biliary Catheter System Kit / Flexima™ Biliary Catheter System with Radiopaque Marker / Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip / Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip and Radiopaque Marker.

Indications for Use *(Describe)*

The Flexima™ Ureteral Stent System and Flexima™ Ureteral Stent System Kit is intended to provide drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally.

The Flexima™ Biliary Catheter System / Flexima™ Biliary Catheter System Kit / Flexima™ Biliary Catheter System with Radiopaque Marker / Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip / Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip and Radiopaque Marker are intended to provide external and internal percutaneous drainage of the biliary system.

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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510(k) Summary

510(k) Summary Complying with 21 CFR 807.92

I. SUBMITTER INFORMATION

Submitter name: Boston Scientific Corporation

Submitter address:
Three Scimed Place
Maple Grove, MN 55311-1566
USA

Telephone: 763-494-2211
Fax: 763-494-2222
e-mail: JoisDayana.ZunigaGamboa@bsci.com

Contact person name: Jois Zuniga G.
Date Prepared: December 11, 2019

II. DEVICE INFORMATION

Table 1, 2 and 3 as follows summarizes the relevant device information for the subject devices.

Table 1. Flexima™ Biliary Catheters Name of Devices

Device Trade Name	Model Number
Flexima™ Biliary Catheter System	M001271540
	M001271550
	M001271560
	M001271570
	M001271580
	M001271590
	M001271600
	M001271610
	M001271620
Flexima™ Biliary Catheter System Kit	M001271630
	M001271640
	M001271650
	M001271660

Device Trade Name	Model Number
Flexima™ Biliary Catheter System with Radiopaque Marker	M001272600
	M001272610
	M001272620
	M001272630
	M001272640
	M001272650
	M001272660
	M001272670
Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip	M001281560
	M001281570
	M001281580
	M001281590
Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip and Radiopaque Marker	M001282610
	M001282600

Table 2. Flexima™ Ureteral Stents Name of Devices

Device Trade Name	Model Number
Flexima™ Ureteral Stent System	M001274000
	M001274010
	M001274020
	M001274030
	M001274040
	M001274050
	M001274060
	M001274070
	M001274080
	M001274090
Flexima™ Ureteral Stent System Kit	M001274100
	M001274110
	M001274120
	M001274130
	M001274140
	M001274150
	M001274160
	M001274170
	M001274180
	M001274190

Table 3 Additional Device Information

Common or Usual Name	Classification Number	Classification Name	Product Code	Product Code Name	Regulatory Class
Biliary Drainage Catheters	21 CFR Part 876.5010	Biliary catheter and accessories	FGE	stents, drains and dilators for the biliary ducts.	II
Ureteral Stent Systems	21 CFR Part 876.4620	Ureteral stent	FAD	stent, ureteral	II

III. PREDICATE DEVICE IDENTIFICATION

Name of Predicate Device

Flexima Biliary Catheter K023870 (Predicate for Flexima Biliary Catheters)

Flexima Drainage Catheters and Stents K944290 (Predicate for Flexima Ureteral Stents)

Predicate devices referenced above have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Flexima Biliary Catheters are constructed of Flexima, a Tecoflex Polyeurethane-based resin, and selected subfamilies also have a radiopaque marker (RO) made from 65%Tungsten. The radiopaque marker is located approximately 5mm proximal to the most proximal drainage hole to aid in proper placement of the catheter. Additionally, designated Flexima Biliary Catheters are available with a biocompatible, dissolving distal tip (Temp-Tip™). This dissolvable tip facilities tracking over a guidewire for percutaneous placement and dissolves within 24 hours of placement to provide a larger drainage lumen. These biliary catheters provide external and internal percutaneous drainage of the biliary system. Where long-term use is indicated, it is recommended that indwelling time not exceed 90 days.

The Flexima Ureteral Stent is also constructed of Tecoflex Polyeurethane-based resin. The pigtails on either end of the stent, are in opposite directions so that the proximal pigtail can form in the renal pelvis, while the distal pigtail forms in the bladder, to provide drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally. The double pigtail stent prevents upward and downward movement. Also, where long-term use is indicated, this stent is recommended not to exceed 90 days of indwelling time.

The Flexima Biliary Catheters and Flexima Ureteral Stents are provided sterile, using 100% ethylene oxide (EO) gas sterilization, and are intended for hospital and single use only. These devices utilize Glidex™ Hydrophillic Coating for the reduction of surface friction during placement.

Table 4 and Table 5 below provide information on the differences between the models, in relation to the outside diameter and length dimensions of the Flexima Biliary Catheters and Flexima Ureteral Stents respectively.

Table 4. Flexima Biliary Catheters Dimensions

Product Trade Name	Model Number	Dimensions (OD/Length)
Flexima™ Biliary Catheter System	M001271540	8F/35cm
	M001271550	10F/35cm
	M001271560	8F/35cm
	M001271570	10F/35cm
	M001271580	12F/35cm
	M001271590	14F/35cm
	M001271600	10F/35cm
	M001271610	12F/35cm
	M001271620	14F/35cm
Flexima™ Biliary Catheter System Kit	M001271630	8F/35cm
	M001271640	10F/35cm
	M001271650	8F/35cm
	M001271660	10F/35cm
Flexima™ Biliary Catheter System with Radiopaque Marker	M001272600	8F/35cm
	M001272610	10F/35cm
	M001272620	12F/35cm
	M001272630	14F/35cm
	M001272640	8F/35cm
	M001272650	10F/35cm
	M001272660	10F/35cm
	M001272670	12F/35cm
Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip	M001281560	8F/35cm
	M001281570	10F/35cm
	M001281580	12F/35cm
	M001281590	14F/35cm
Flexima™ Biliary Catheter System with Hydrophilic Dissolving Tip and Radiopaque Marker	M001282600	8F/35cm
	M001282610	10F/35cm

Table 5. Flexima Ureteral Stents Dimensions

Product Trade Name	Model Number	Dimensions (OD/Length)
Flexima™ Ureteral Stent System	M001274000	8F/20cm
	M001274010	8F/22cm
	M001274020	8F/24cm
	M001274030	8F/26cm
	M001274040	8F/28cm
	M001274050	10F/20cm
	M001274060	10F/22cm
	M001274070	10F/24cm
	M001274080	10F/26cm
	M001274090	10F/28cm
Flexima™ Ureteral Stent System Kit	M001274100	6F/20cm
	M001274110	6F/22cm
	M001274120	6F/24cm
	M001274130	6F/26cm
	M001274140	6F/28cm
	M001274150	8F/20cm
	M001274160	8F/22cm
	M001274170	8F/24cm
	M001274180	8F/26cm
	M001274190	8F/28cm

V.INDICATIONS FOR USE

Flexima Biliary Catheters
To provide external and internal percutaneous drainage of the biliary system.

Flexima Ureteral Stents
To provide drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally.

Predicate and subject device Intended use and Indications for Use are the same.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

There are no differences in the technological characteristics between the predicate and subject devices. The Flexima Biliary Catheters and Flexima Ureteral Stents maintain the same fundamental scientific technology, indications for use and operating principles as the predicate devices - K023870 and K944290 respectively.

The purpose of this 510(k) submission is to receive clearance for the addition of MRI Magnetic Resonance information to the product directions for use (DFU).

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

In order to support the addition of Magnetic Resonance Safety Information to the Directions for Use the following non-clinical performance testing was performed:

- Radio Frequency Heating
- Force Measurement
- Image Artifact

FDA guidance *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment. Dec. 2014* and the following standards were used to guide the generation of the non-clinical data:

Document Name	Document Number	Document Version
Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging	ASTM F2182	-11a
Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	ASTM F2052	− 14
Evaluation of MR Image Artifacts from Passive Implants	ASTM F2119	– 07

VIII. CONCLUSION

Based on the intended use, technological characteristics, and non-clinical performance data provided, the Biliary Drainage Catheters and the Ureteral Stent Systems are substantially equivalent to the predicate devices K944290 and K023870 respectively. The Directions for Use update with magnetic resonance safety information for the subject devices does not raise new questions of safety or effectiveness, and the subject devices are as safe and effective as the predicate devices.