April 26, 2021

Boston Scientific Corporation
Heidi Shearer
Senior Regulatory Affairs Specialist
Three Scimed Place
Maple Grove, MN 55311

Re: K200260
Trade/Device Name: Percuflex™ Ureteral Stent System and Percuflex™ Ureteral Stent System Kit, Percuflex™ Nephroureteral Stent System, Amplatz Anchor™ Catheter System
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD, FGE
Dated: March 25, 2021
Received: March 26, 2021

Dear Heidi Shearer:

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 Percuflex Ureteral Stent System 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.
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)*
K200260

Device Name
Percuflex™ Ureteral Stent System and Percuflex™ Ureteral Stent System Kit,
Percuflex™ Nephroureteral Stent System
Amplatz Anchor™ Catheter System

Indications for Use *(Describe)*
Percuflex™ Ureteral Stent System and Percuflex™ Ureteral Stent System Kit:
The Ureteral Stent 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.

Percuflex™ Nephroureteral Stent System:
The Percuflex Nephroureteral Stent is intended for use in Percutaneous Drainage to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent.

Amplatz Anchor™ Catheter System:
The Amplatz Anchor™ Catheter System is intended for use in applications of percutaneous drainage, particularly percutaneous nephrostomy, abscess or external biliary drainage.

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.

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510(k) Summary - K200260

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: 763-255-0056
Fax: 763-494-2222
e-mail: Heidi.Shearer@bsci.com

Contact person name: Heidi Shearer
Date Prepared: April 26, 2021

II. DEVICE INFORMATION

Tables 1 to 4 below summarize the relevant subject device information.

Table 1: Percuflex™ Ureteral Stent System and Percuflex™ Ureteral Stent System Kit

Product Trade Name	Model Numbers
Percuflex™ Ureteral Stent System	M001235490
	M001235500
	M001235510
	M001235520
	M001235530
	M001235570
	M001235580
	M001235590
	M001235600
	M001235610
	M001245490
	M001245500
	M001245510
	M001245520
	M001245530
	M001245570
	M001245580

510(k) Summary
Percuflex Drainage Catheters and Stents

Product Trade Name	Model Numbers
	M001245590
	M001245600
	M001245610
Percuflex™ Ureteral Stent System Kit	M001245620
	M001245630
	M001245640
	M001245650
	M001245660
	M001245720
	M001245730
	M001245740
	M001245750
	M001245760

Table 2: Percuflex™ Nephroureteral Stent System

Product Trade Name	Model Number
Percuflex™ Nephroureteral Stent System	M001221360
	M001221370
	M001221380
	M001221390
	M001221400
	M001221410
	M001221420
	M001221430
	M001231360
	M001231370
	M001231380
	M001231390
	M001231400
	M001231410
	M001231420
	M001231430

Table 3: Amplatz Anchor™ Catheter System

Product Trade Name	Model Number
Amplatz Anchor™ Catheter System	M001221000
	M001221010
	M001221020

Table 4: Additional Device Information

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

III. PREDICATE DEVICE IDENTIFICATION

Name of Predicate Device
Medi-Tech Ureteral Stent System, Nephroureteral Stent System, Amplatz Anchor System with Locking Malecot (K924608, Cleared 26-Jan-1994)

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

IV. DEVICE DESCRIPTION

The Percuflex™ Ureteral Stent System and Percuflex™ Ureteral Stent System Kit is designed with the classic pigtail shape on each end and is intended to facilitate drainage internally from the renal pelvis to the bladder and stenting of the ureter without external access after placement. The ureteral stent systems contain a suture to adjust the pigtail shape or to remove the stent. These devices are constructed of a proprietary, biocompatible copolymer called Percuflex™ for patient comfort with a radiopaque resin throughout the catheter tube. Designated Percuflex™ Ureteral Stent Systems are also available with a proprietary Glidex™ hydrophilic material for the reduction of surface friction during placement or with a dissolving distal tip (Temp-Tip™). The dissolving tip internal diameter aids in placement, then dissolves soon after placement to allow a larger lumen for drainage.

The Percuflex™ Nephroureteral Stent System is also designed with the classic pigtail shape on each end and facilitates drainage from the internal ureteropelvic junction to the bladder with external access to the stent. The Nephroureteral Stent System also incorporates the Percuflex™ copolymer and a radiopaque resin throughout the catheter tube. Select models are available with a Temp-Tip™ which dissolves soon after placement. A suture is locked in place with a stopcock to retain the pigtail shape. A luer allows for connection to other drainage devices with a conical fitting.

The Amplatz Anchor™ Catheter System is designed with a unique locking Malecot diamond shape to facilitate percutaneous nephrostomy, abscess or external biliary drainage. The Amplatz Anchor™ Catheter Systems also incorporate the Percuflex™ copolymer and a radiopaque resin throughout the catheter tube. A suture is locked in place with a stopcock to retain the 2-wing design. A luer allows for connection to other drainage devices with a conical fitting.

510(k) Summary
Percuflex Drainage Catheters and Stents

These Percuflex™ Drainage Catheters and Stents are provided sterile, using 100% ethylene oxide (EO) gas sterilization, and are intended for hospital and single use only. Where long-term use is indicated, it is recommended not to exceed 90 days of indwelling time.

Table 5, 6, and 7 below provide information on the differences between the Percuflex™ Drainage Catheters and Stents models, in relation to specific device features such as coating, dissolving tip, and the outside diameter and length dimensions.

Table 5: Percuflex™ Ureteral Stent System Device Features

Product Trade Name	Product Labeled Features	Model Number	Dimensions (OD/Length)
Percuflex™ Ureteral Stent System	Percuflex™ TempTip™ Ureteral Stent System with Dissolving Tip	M001235490	8F/20cm
		M001235500	8F/22cm
		M001235510	8F/24cm
		M001235520	8F/26cm
		M001235530	8F/28cm
		M001235570	10F/20cm
		M001235580	10F/22cm
		M001235590	10F/24cm
		M001235600	10F/26cm
		M001235610	10F/28cm
	Percuflex™ Glidex™ HYDROGEL COATING Ureteral Stent System	M001245490	8F/20cm
		M001245500	8F/22cm
		M001245510	8F/24cm
		M001245520	8F/26cm
		M001245530	8F/28cm
		M001245570	10F/20cm
		M001245580	10F/22cm
		M001245590	10F/24cm
		M001245600	10F/26cm
		M001245610	10F/28cm
Percuflex™ Ureteral Stent System Kit	Percuflex™ Glidex™ HYDROGEL COATING Ureteral Stent System Kit	M001245620	8F/20cm
		M001245630	8F/22cm
		M001245640	8F/24cm
		M001245650	8F/26cm
		M001245660	8F/28cm

Product Trade Name	Product Labeled Features	Model Number	Dimensions (OD/Length)
		M001245720	6F/20cm
		M001245730	6F/22cm
		M001245740	6F/24cm
		M001245750	6F/26cm
		M001245760	6F/28cm

Table 6: Percuflex™ Nephroureteral Stent System Device Features

Product Trade Name	Product Labeled Features	Model Number	Dimensions (OD/Length)
Percuflex™ Nephroureteral Stent System	Percuflex™ Locking Pigtail Nephroureteral Stent System	M001221360	8F/22cm
		M001221370	8F/24cm
		M001221380	8F/26cm
		M001221390	8F/28cm
		M001221400	10F/22cm
		M001221410	10F/24cm
		M001221420	10F/26cm
		M001221430	10F/28cm
	Percuflex™ TempTip™ Locking Pigtail Nephroureteral Stent System with Dissolving Tip	M001231360	8F/22cm
		M001231370	8F/24cm
		M001231380	8F/26cm
		M001231390	8F/28cm
		M001231400	10F/22cm
		M001231410	10F/24cm
		M001231420	10F/26cm
		M001231430	10F/28cm

Table 7: Amplatz Anchor™ Catheter System Device Features

Product Trade Name	Product Labeled Features	Model Number	Dimensions (OD/Length)
Amplatz Anchor™ Catheter System	Amplatz Anchor™ Locking Malecot, Amplatz Anchor Catheter System	M001221000	8F/30cm
		M001221010	10F/30cm
		M001221020	12F/30cm

510(k) Summary
Percuflex Drainage Catheters and Stents

V. INDICATIONS FOR USE

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

Percuflex™ Drainage Catheters and Stents	Indications for Use
Percuflex™ Ureteral Stent System and Percuflex™ Ureteral Stent System Kit	The Ureteral Stent 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.
Percuflex™ Nephroureteral Stent System	The Percuflex Nephroureteral Stent is intended for use in Percutaneous Drainage to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent.
Amplatz Anchor™ Catheter System	The Amplatz Anchor™ Catheter System is intended for use in applications of percutaneous drainage, particularly percutaneous nephrostomy, abscess or external biliary drainage.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Percuflex™ Drainage Catheters and Stents incorporate substantially equivalent design, function, packaging, sterilization process, materials, fundamental technology, indications for use, and operating principles as those featured in the predicate drainage devices (K924608). The difference from the legally marketed predicate device is the addition of Magnetic Resonance (MR) compatibility information to the Directions for Use.

Cumulative changes have been made to the devices internally through Boston Scientific's Design Control System, which meets the quality system regulation requirements of 21 CFR Part 820. These changes include a resin additive material supplier change and tensile performance specification update.

The tensile performance specification update applies to the Percuflex™ TempTip™ Ureteral Stent System with Dissolving Tip and the Percuflex™ TempTip™ Locking Pigtail Nephroureteral Stent System with Dissolving Tip devices. This change updated the dissolving tip to catheter tensile strength performance specification.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

In order to support the addition of Magnetic Resonance Compatibility 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 (December 11, 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

In order to support the cumulative changes that have been made to the devices internally through Boston Scientific's Design Control System, the following non clinical performance testing was performed:

- Resin additive material supplier change
    - A material evaluation consisted of Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), Thermogravimetric Analysis (TGA), Oxidative Induction Time (OIT), and Dynamic Contact Angle (DCA) analysis was performed. Results demonstrated that both supplied resins present the same thermal transition characteristics, material type (chemistry), and composition.
    - Design Verification testing including Catheter Shaft Tensile, Column Strength, Kink Resistance, Removal Force, and Renal Coil Resistance-Stent Shaft >5F was performed to assess these finished device properties.
    - The following biocompatibility testing was performed per ISO 10993-1:
        - Cytotoxicity
        - Sensitization
        - Intracutaneous irritation testing
        - Material mediated pyrogenicity
        - Acute systemic toxicity testing
        - Genotoxicity testing – Ames assay
        - Genotoxicity testing – MLA
        - Muscle implantation – 4-week study
        - Muscle implantation – 13-week study
        - Toxicological Risk Assessment

- Tensile performance specification update
    - Design verification testing was conducted on aged and unaged samples to demonstrate the dissolving tip to shaft bond design output continues to meet the defined design input requirements after sterilization.

- **CONCLUSION**
  Based on the intended use, technological characteristics, and non-clinical performance data provided, the Percuflex™ Drainage Catheters and Stents are substantially equivalent to the predicate devices (K924608). The Directions for Use update with magnetic resonance compatibility 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.