April 15, 2025

Boston Scientific Corporation
Stephanie Anderson
Regulatory Affairs Specialist
100 Boston Scientific Way
Urology and Pelvic Health Division
Marlborough, Massachusetts 01752

Re: K250824
Trade/Device Name: Percuflex Ureteral Stent; Percuflex Plus Ureteral Stent; Percuflex Plus SureDrive Steerable Ureteral Stent Set; Contour Ureteral Stent; Contour SureDrive Steerable Ureteral Stent Set; Contour VL Variable Length Ureteral Stent; Contour VL SureDrive Steerable Ureteral Stent Set; Polaris Ultra Ureteral Stent; Polaris Loop Ureteral Stent; Tria Firm Ureteral Stent; Tria Soft Ureteral Stent; Percuflex Urinary Diversion Stent Set
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: March 18, 2025
Received: March 18, 2025

Dear Stephanie Anderson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Angel A. Soler-garcia -S

for
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250824

Device Name
Percuflex Ureteral Stent; Percuflex Plus Ureteral Stent; Contour Ureteral Stent; Contour VL Variable Length Ureteral Stent; Polaris Ultra Ureteral Stent; Polaris Loop Ureteral Stent; Tria Firm Ureteral Stent; Tria Soft Ureteral Stent;

Indications for Use *(Describe)*
The Ureteral Stents are intended to facilitate urinary drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250824

Device Name
Percuflex Plus SureDrive Steerable Ureteral Stent Set; Contour SureDrive Steerable Ureteral Stent Set; Contour VL SureDrive Steerable Ureteral Stent Set;

Indications for Use *(Describe)*
The Ureteral Stent Sets are intended to facilitate urinary drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250824

Device Name
Percuflex Urinary Diversion Stent Set

Indications for Use *(Describe)*
The Urinary Diversion Stent Sets are intended to provide external drainage of urine after urinary diversion surgeries.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for Ureteral Stents and Urinary Diversion Stent Set

Date Prepared: 18Mar2025

A. Submitter

Boston Scientific Corporation
Urology Division
100 Boston Scientific Way
Marlborough, MA 01752

B. Contacts

Stephanie Anderson
Regulatory Affairs Specialist
763-255-0028
Stephanie.Anderson2@bsci.com

C. Device Names

Common Name	Trade Name	Product code	Regulation	Classification
Ureteral Stent	Percuflex™ Ureteral Stent	FAD	21 CFR 876.4620 – Ureteral Stent	Class II
	Percuflex™ Plus Ureteral Stent			
	Percuflex™ Plus SureDrive™ Steerable Ureteral Stent Set			
	Contour™ Ureteral Stent			
	Contour™ SureDrive™ Steerable Ureteral Stent Set			
	Contour VL™ Variable Length Ureteral Stent			
	Contour VL™ SureDrive™ Steerable Ureteral Stent Set			
	Polaris™ Ultra Ureteral Stent			
	Polaris™ Loop Ureteral Stent			
	Tria™ Firm Ureteral Stent			
	Tria™ Soft Ureteral Stent			
Nephrostomy Catheter	Percuflex™ Urinary Diversion Stent Set	LJE	Pre-Amendment, Unclassified	Class II

D. Predicate and Reference Devices

For the purpose of establishing 'substantial equivalence', the design and technological characteristics of the proposed Ureteral Stents and Urinary Diversion Stent Set were compared to the following 510(k)-cleared device.

Predicate Device for Establishing 'Substantial Equivalence'

	Predicate Device
Device Trade Name:	Tria™ Firm Ureteral Stent
Regulation Name:	Ureteral Stent
Regulation Number:	21 CFR 876.4620
Classification:	Class II
Product Code:	FAD
510(k) Submitter/Holder:	Boston Scientific Corporation Marlborough, MA
510(k) #/Clearance Date:	K190603 Cleared May 24, 2019

E. Device Description

The Ureteral Stents are sterile, single use, disposable devices that provide a lumen that allows fluids to move from the kidney to the bladder. The Ureteral Stents are provided in multiple French sizes and lengths.

The Urinary Diversion Stent Sets are sterile, single use, disposable devices that allow internal drainage from the kidney to an external collection system.

F. Intended Use/Indications for Use

The changes proposed within this bundled Special 510(k) are to update the labeling, including the indications for use, for the proposed Ureteral Stents with minor changes from the predicate to align with state-of-the-art clinical use and to clarify and consolidate language across product families. The changes do not represent an expansion in indications as they do not describe a new disease, condition or patient population that the devices are intended in diagnosing, treating, preventing, curing or mitigating.

Proposed Ureteral Stents Indications for Use:
The Ureteral Stents are intended to facilitate urinary drainage from the kidney to the bladder via placement endoscopically or fluoroscopically by a trained physician.

The indications for use for the proposed Urinary Diversion Stent Sets is similar to the predicate device as it is intended to provide urinary drainage, however the Urinary Diversion Stent Sets drain to an external collection system.

Proposed Urinary Diversion Stent Sets Indications for Use:
The Urinary Diversion Stent Sets are intended to provide external drainage of urine after urinary diversion surgeries.

G. Operating Principle

The Ureteral Stents are available in various lengths and diameters and include an attached retrieval line (suture) for use during placement or removal. Stents are designed with the ability to be placed over a guidewire. The dual pigtail design is intended to help maintain stent position after placement in the ureter and prevent migration. The stent shaft and both pigtails contain side ports to facilitate drainage into the bladder. The single pigtail design is intended to help

maintain the stent position after placement in the ureter. Ureteral Stents are constructed with a radiopaque material to improve visualization during placement.

The Urinary Diversion Stent measures approximately 80 cm from the kidney coil to the distal end. The stent body is straight except at the kidney end, which is shaped into a pigtail type design to allow for better stent positioning within the kidney. The pigtail design is intended to help maintain stent position after placement in the kidney and prevent migration. Both the stent shaft and pigtail contain side ports to facilitate drainage to an external collection system following urinary diversion procedures. Stents are designed with the ability to be placed over a guidewire.

H. Comparison of Key Technological/Performance Characteristics

The proposed Ureteral Stents and Urinary Diversion Stent Sets have the same (or similar) technological characteristics and fundamental design as the predicate device.

The principles of operation are the same between the predicate and proposed devices. The Ureteral Stents provide a lumen that allows fluids to move from the kidney to the bladder. The Urinary Diversion Stent Sets provide a lumen that allows internal drainage from the kidney to an external collection system.

The technological characteristics of the proposed devices remain equivalent to the predicate device because the modifications that are the subject of this Special 510(k) submission are limited to the labeling for the proposed devices and do not include changes to the overall design, performance, operating principle or fundamental technology.

I. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the proposed Ureteral Stents and Urinary Diversion Stent Sets are substantially equivalent to the predicate device with respect to intended use, operating principle, and technological characteristics. The differences between the proposed and predicate devices do not alter the suitability of the proposed devices for their intended use.

J. Performance Testing

The changes proposed within this bundled Special 510(k) are to the labeling for the proposed devices. There are no changes in design, performance, operating principle, or fundamental technology being proposed within this premarket notification. Therefore, existing test information/data remains valid for the proposed devices. No additional Verification or Validation testing was required for the changes to the labeling.

There are no differences between the proposed devices and the predicate device that could affect the shelf-life, sterility or biocompatibility; therefore, shelf-life, sterilization and biocompatibility evaluations were not required.

K. Conclusion

Based on the intended use/indications for use, operating principle and comparison of key technological characteristics presented in this premarket notification, it is concluded that the

proposed Ureteral Stents and Urinary Diversion Stent Set are substantially equivalent to the predicate device (cleared under K190603).