May 24, 2019

Boston Scientific Corporation
Justin Kapitan
Senior Regulatory Affairs Specialist
Urology and Pelvic Health
100 Boston Scientific Way
Marlborough, MA 01752

Re: K190603
Trade/Device Name: Tria Firm Ureteral Stent
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: April 22, 2019
Received: April 24, 2019

Dear Justin Kapitan:

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,

for
Glenn Bell, 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)*
K190603

Device Name
Tria Firm Ureteral Stent

Indications for Use *(Describe)*
The Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically, fluoroscopically or during an open surgical procedure 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:

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*"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."*

## SECTION 5 510K SUMMARY

### 510(k) Summary for the Tria Firm Ureteral Stent

**A. Sponsor**

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01752

**B. Contact**

Justin Kapitan
Sr. Regulatory Affairs Specialist
508-683-4518
justin.kapitan@bsci.com

or

Virginia Garcia
Regulatory Affairs Manager
508-683-4430
Virginia.garcia@bsci.com

**C. Proposed Device**

| | |
|---|---|
| Trade name: | Tria Firm Ureteral Stent |
| Common/usual name: | Stent, Ureteral |
| Classification Number: | 21 CFR 876.4620 |
| Classification Name: | Ureteral Stent |
| Classification: | Class II |
| Product Code: | FAD |
| Product Code Name: | Stent, Ureteral |

**D. Predicate Device**

| | |
|---|---|
| Trade name: | Tria Firm Ureteral Stent |
| Common/usual name: | Stent, Ureteral |
| Classification Number: | 21 CFR 876.4620 |
| Classification Name: | Ureteral Stent |
| Classification: | Class II |
| Product Code: | FAD |
| Product Code Name: | Stent, Ureteral |

Identification of Predicate Device: Tria Firm Ureteral Stent, K163399

**SECTION 5** **510K SUMMARY**

## E. Model Name and Model Numbers

| Model Number | Model Name | Size (Fr x cm) |
|---|---|---|
| M0061902050 | Tria Firm Ureteral Stent | 4.8x10 |
| M0061902060 | Tria Firm Ureteral Stent | 4.8x12 |
| M0061902070 | Tria Firm Ureteral Stent | 4.8x14 |
| M0061902080 | Tria Firm Ureteral Stent | 4.8x16 |
| M0061902090 | Tria Firm Ureteral Stent | 4.8x18 |
| M0061902100 | Tria Firm Ureteral Stent | 4.8x20 |
| M0061902110 | Tria Firm Ureteral Stent | 4.8x22 |
| M0061902120 | Tria Firm Ureteral Stent | 4.8x24 |
| M0061902130 | Tria Firm Ureteral Stent | 4.8x26 |
| M0061902140 | Tria Firm Ureteral Stent | 4.8x28 |
| M0061902150 | Tria Firm Ureteral Stent | 4.8x30 |
| M0061902200 | Tria Firm Ureteral Stent | 6x20 |
| M0061902210 | Tria Firm Ureteral Stent | 6x22 |
| M0061902220 | Tria Firm Ureteral Stent | 6x24 |
| M0061902230 | Tria Firm Ureteral Stent | 6x26 |
| M0061902240 | Tria Firm Ureteral Stent | 6x28 |
| M0061902250 | Tria Firm Ureteral Stent | 6x30 |
| M0061902300 | Tria Firm Ureteral Stent | 7x20 |
| M0061902310 | Tria Firm Ureteral Stent | 7x22 |
| M0061902320 | Tria Firm Ureteral Stent | 7x24 |
| M0061902330 | Tria Firm Ureteral Stent | 7x26 |
| M0061902340 | Tria Firm Ureteral Stent | 7x28 |
| M0061902350 | Tria Firm Ureteral Stent | 7x30 |
| M0061902400 | Tria Firm Ureteral Stent | 8x20 |
| M0061902410 | Tria Firm Ureteral Stent | 8x22 |
| M0061902420 | Tria Firm Ureteral Stent | 8x24 |
| M0061902430 | Tria Firm Ureteral Stent | 8x26 |
| M0061902440 | Tria Firm Ureteral Stent | 8x28 |
| M0061902450 | Tria Firm Ureteral Stent | 8x30 |

**SECTION 5 510K SUMMARY**

| Model Number | Model Name | Size (Fr x cm) |
|---|---|---|
| M0061902550 | Tria Firm Ureteral Stent | 4.8x10 |
| M0061902560 | Tria Firm Ureteral Stent | 4.8x12 |
| M0061902570 | Tria Firm Ureteral Stent | 4.8x14 |
| M0061902580 | Tria Firm Ureteral Stent | 4.8x16 |
| M0061902590 | Tria Firm Ureteral Stent | 4.8x18 |
| M0061902600 | Tria Firm Ureteral Stent | 4.8x20 |
| M0061902610 | Tria Firm Ureteral Stent | 4.8x22 |
| M0061902620 | Tria Firm Ureteral Stent | 4.8x24 |
| M0061902630 | Tria Firm Ureteral Stent | 4.8x26 |
| M0061902640 | Tria Firm Ureteral Stent | 4.8x28 |
| M0061902650 | Tria Firm Ureteral Stent | 4.8x30 |
| M0061902700 | Tria Firm Ureteral Stent | 6x20 |
| M0061902710 | Tria Firm Ureteral Stent | 6x22 |
| M0061902720 | Tria Firm Ureteral Stent | 6x24 |
| M0061902730 | Tria Firm Ureteral Stent | 6x26 |
| M0061902740 | Tria Firm Ureteral Stent | 6x28 |
| M0061902750 | Tria Firm Ureteral Stent | 6x30 |
| M0061902800 | Tria Firm Ureteral Stent | 7x20 |
| M0061902810 | Tria Firm Ureteral Stent | 7x22 |
| M0061902820 | Tria Firm Ureteral Stent | 7x24 |
| M0061902830 | Tria Firm Ureteral Stent | 7x26 |
| M0061902840 | Tria Firm Ureteral Stent | 7x28 |
| M0061902850 | Tria Firm Ureteral Stent | 7x30 |
| M0061902900 | Tria Firm Ureteral Stent | 8x20 |
| M0061902910 | Tria Firm Ureteral Stent | 8x22 |
| M0061902920 | Tria Firm Ureteral Stent | 8x24 |
| M0061902930 | Tria Firm Ureteral Stent | 8x26 |
| M0061902940 | Tria Firm Ureteral Stent | 8x28 |
| M0061902950 | Tria Firm Ureteral Stent | 8x30 |

**F. Device(s) Description**

The Tria Firm Ureteral Stent consists of the following:

- Tria™ Firm Ureteral Stent with retrieval line
- Ureteral Stent Positioner

- Pigtail Straightener

**F. Intended Use/Indications for Use**

The Tria Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically, fluoroscopically or during an open surgical procedure by a trained physician.

**G. Technological Characteristics Compared to Predicate**

The principles of operation are identical between the predicate and subject devices: The Tria Firm Ureteral Stent provides a lumen that allows fluids to move from the kidney to the bladder.

The differences between the subject device and the predicate are minor. Differences include:

- Modification of processing of compounded resin used to manufacture the middle layer of the stent. Modification to address cosmetic observations on the final finished device.
- Modification of the performance specification of surface roughness. Modified specification to compare to a predicate device.
- Modification of the position of the laser etched text used for stent identification from the shaft of the stent to the bladder coil.
- Addition of performance specification for accumulation of urine calcium and magnesium salts to align with claims in the Directions for Use cleared under K163399.

The technological characteristics remain equivalent to the predicate device because the modifications that are the subject of this submission are limited to improvements to the existing design.

**H. Substantial Equivalence**

The modified Tria Firm Ureteral Stent is substantially equivalent to the predicate Tria Firm Ureteral Stent (K163399). It has the same intended use for facilitating drainage from the kidney to the bladder and the same indications for use. The system design and principles of operation remain the same.

**I. Biocompatibility**

**SECTION 5 510K SUMMARY**

Biocompatibility testing was performed to show that all patient contacting materials meet applicable biocompatibility standards per **ISO 10993-1:2009** and the FDA guidance: Use of International Standard **ISO 10993-1** "*Biological evaluation of medical devices. Evaluation and testing within a risk management process*."

The following testing was performed with passing results to support the biocompatibility of the device:

- Cytotoxicity
- Sensitization
- Irritation
- Accute Systemic Toxicity
- Materials Mediated Pyrogenicity
- Implantation
- Chemical Characterization with Toxicological Risk Assessment (used to address systemic endpoints)

**J. Performance Testing**

The modifications to the subject Tria Firm Ureteral Stent have been tested in the same manner to ensure compliance to the initial specifications. Based on the change assessment including risk analysis, the following design verification tests were repeated. The test methods used were the same as those submitted for the predicate.

- Removal Force
- Renal Coil Strength
- Tapered Renal Tip
- Retrieval Line to Stent Shaft Tensile Strength
- Appearance and Cleanliness
- Reversibility of Tip Configuration
- Column Strength
- Stent Softens at Body Temperature
- Surface Roughness
- Stent Identification Markers
- Guidewire Compatibility
- Biocompatibility

The device continues to be sterilized by ethylene oxide (EO) to an SAL $10^{-6}$ level.

The conclusion of the assessments demonstrates that the modified device continues to function as intended in a manner equivalent to the predicate device. The modified device raises no new issues of safety or effectiveness compared to the predicate.

**SECTION 5 510K SUMMARY**

**K. Conclusion**

Based on the test data, the same intended use, and same indications for use, the modified Tria Firm Ureteral Stent is substantially equivalent to its predicate, K163399.