DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 22, 2017

Boston Scientific Corporation
Christine Shoemaker
Sr. Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K163399
Trade/Device Name: Tria™ Firm Ureteral Stent
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: May 19, 2017
Received: May 22, 2017

Dear Christine Shoemaker:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163399

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.

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SECTION 5 510(k) SUMMARY

510(k) Summary for Tria™ Firm Ureteral Stent

A. Sponsor

Boston Scientific Corporation
Urology and Pelvic Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

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Or
Lisa Sullivan
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Date Prepared: June 21, 2017

C. Device Name

Trade name: Tria™ Firm Ureteral Stent
Common/usual name: stent, ureteral
Classification Name: FAD – Stent, Ureteral

D. Predicate and Reference Devices

Predicate Trade name: Contour™ Ureteral Stent (Boston Scientific)
Common/usual name: stent, ureteral
Classification Name: FAD – Stent, Ureteral
Premarket Notification: Contour™ (Modified Ureteral Indwelling Catheter/Stent) Ureteral Stent, K974541, Sep 02, 1998.
The Contour Ureteral Stent has not been the subject of a design-related recall.

Reference 1 Trade name: Percuflex™ Ureteral Stent (Boston Scientific)
Common/usual name: stent, ureteral
Classification Name: FAD – Stent, Ureteral
Premarket Notification: K834468, Apr 20, 1984.

Reference 2 Trade name: Advantix™ Pancreatic Stent (Boston Scientific)
Common/usual name: Biliary Catheters and Accessories
Classification Name: FGE – Biliary Catheter and accessory
Premarket Notification: K133700, May 14, 2014.

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Reference 3 Trade name: InLay Optima® Ureteral Stent (Bard)
Common/usual name: stent, ureteral
Classification Name: FAD – Stent, Ureteral
Premarket Notification: K022447, Jan 23, 2003.

E. Device Description

The Tria™ Firm Ureteral Stent is intended to facilitate drainage from the kidney to the bladder via placement endoscopically or fluoroscopically or during an open surgical procedure. It is constructed of the same Percuflex polymer as other stents currently marketed by BSC. Tria Firm utilizes a modified extrusion process to provide ureteral stents with an ultra-smooth surface topography.

The Tria™ Firm stent has a double pigtail design and utilizes the same monofilament retrieval lines that are used on other BSC ureteral stents. Tria Firm is packaged with a standard straight stent positioner and a pigtail straightener that are currently provided with other ureteral stents marketed by Boston Scientific.

The purpose of the Tria™ Firm Ureteral Stent is to provide physicians with a product that is aimed at addressing accumulation of urine salt deposits during indwelling. The proprietary surface technology on both the outside and inside of the stent provides maximum coverage from calcium and magnesium salt deposition.

In vitro testing conducted on the Tria™ Firm Ureteral Stent showed a statistically significant lower level of urine calcium and magnesium salt accumulation on the stent surface compared to competitive devices. Correlation of *in vitro* data to clinical outcomes have not been established.

F. Intended Use

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.

G. Technological Characteristics

The proposed Tria™ Firm Ureteral Stents have the same technological characteristics, fundamental ureteral stent design, and types of materials as the predicate device. A modified extrusion process provides an ultra-smooth surface. The device is packed using a thermoformed, multi-product tray. The lidded tray is then placed in a poly/Tyvek pouch that is heat sealed and labeled. The labeled pouch is placed into a labeled shelf carton along with a DFU.

H. Substantial Equivalence

A direct comparison of key characteristics has been performed and demonstrates that the proposed Tria™ Firm Ureteral Stent is substantially equivalent to the predicate device in terms of intended use, technological characteristics, types of

SECTION 5 510(k) SUMMARY

materials and performance characteristics. The proposed Tria Firm Ureteral Stent is as safe, as effective, and performs as well as the predicate device.

I. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with samples aged at T=0 and 13-months Accelerated Aging in support of the new ureteral stent. Third party testing was performed in support of new claims for 1) minimizing the accumulation of urine calcium and magnesium salts, both with and without the presence of bacteria[1] and 2) the proprietary surface technology on both the outside and inside of the stent providing maximum coverage from calcium and magnesium salt deposition .

The results of the testing listed below support the determination of substantial equivalence.

- Performance testing – bladder coil length, renal coil length/shape, working length, flow rate, surface roughness, MRI safety assessment
- Structural integrity testing – removal force (tensile strength), retrieval line to stent shaft tensile, column strength
- Biological safety testing (biocompatibility)
- Sterile barrier testing

J. Biocompatibility Testing

The following testing was performed to support the biocompatibility of the stents:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Muscle Implantation
- Material Mediated Pyrogenicity
- Chemical analysis – extractables
- Risk assessment of potential toxicity

K. Conclusions

Based on the information and data provided in this Traditional 510(k), the Tria™ Firm Ureteral Stents are substantially equivalent in intended use, design, principle of operation, technology, materials, and performance to the predicate Contour Ureteral Stents (K974541) and are safe and effective for their intended use. Tria Firm was also demonstrated to be substantially equivalent for specific properties when compared to other reference devices (BSC Percuflex (K834468), BSC Advantix (K133700), and Bard Inlay Optima (K022447)).

[1] *Proteus mirabilis* was used as the microbial challenge due to its known urease production.