August 16, 2019

Boston Scientific Corporation
Justin Kapitan
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, MA 01752

Re: K191609
Trade/Device Name: Tria Soft Ureteral Stent
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral stent
Regulatory Class: Class II
Product Code: FAD
Dated: June 14, 2019
Received: June 17, 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/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,

for Glenn B. Bell, Ph.D.
Assistant Division 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)*
K191609

Device Name
Tria Soft 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.

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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 Soft 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

Yunus Gulmez
Regulatory Affairs Specialist II
508-683-5998
Yunus.Gulmez@bsci.com

C. Proposed Device

Trade name:	Tria Soft 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, K190603

SECTION 5 510K SUMMARY

E. Model Name

Tria™ Soft Ureteral Stent

F. Device(s) Description

The Tria Soft Ureteral Stent consists of the following:

- Tria™ Soft Ureteral Stent with retrieval line
- Ureteral Stent Positioner
- Pigtail Straightener

F. Intended Use/Indications for 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 Compared to Predicate

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

The difference between the subject device and the predicate is a minor material change to support the lower durometer of the proposed device.

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.

The proposed changes do not change the intended use nor fundamentally change the scientific technology of the device, and do not change the indications for use of the device.

H. Substantial Equivalence

The modified Tria Soft Ureteral Stent is substantially equivalent to the predicate Tria Firm Ureteral Stent (K190603). It has the same intended use for facilitating drainage from the kidney to the bladder and the same indications for use. The design and principles of operation remain the same.

I. Biocompatibility

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

SECTION 5 510K SUMMARY

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 Soft Ureteral Stent have been tested in the same manner as the predicate 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.

- Dimensions
- Tensile strength tests
- Full Functional tests
- Packaging tests
- Biocompatibility
- Sterility

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.

K. Conclusion

Based on the test data, the same intended use, and same indications for use, the modified Tria Soft Ureteral Stent is substantially equivalent to its predicate, K190603.