April 10, 2018

Boston Scientific Corporation
Daniel FitzDaniel
Regulatory Affairs Specialist
100 Boston Scientific Way
Marlborough, Massachusetts 01752

Re: K180530
Trade/Device Name: Imager™ II Urology Torque Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: KOD
Dated: April 5, 2018
Received: April 6, 2018

Dear Daniel FitzDaniel:

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.

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.

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,

Joyce M. Whang -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180530

Device Name
Imager™ II Urology Torque Catheter

Indications for Use *(Describe)*
The Imager II Urology Torque Catheter is indicated for use in facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the infusion of radiopaque contrast material. The Imager II Urology Torque Catheter is also indicated for the infusion of gels, such as BackStop™, intended for use in the urinary tract.

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."

SECTION 7.
510(K) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Dan FitzDaniel
Regulatory Affairs Specialist
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough MA 01752
Email: dan.fitzdaniel@bsci.com
Tel: (508) 683-4156
Fax: (508) 683-5827

Secondary Contact: Virginia Garcia
Regulatory Affairs Manager
Boston Scientific Corporation
100 Boston Scientific Way
Marlborough MA 01752
Email: virginia.garcia@bsci.com
Tel: (508) 683-4430
Fax: (508) 683-5827

Date Prepared: 10 April 2018

2. Proposed Device:

Trade Name: Imager™ II Urology Torque Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Common Name: Catheter, Urological
Product Code: KOD

3. Predicate Device:

Trade name: Imager™ II Urology Torque Catheter
Clearance Number: K102527
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Common Name: Catheter, Urological
Product Code: KOD

4. Device Description:

The Imager II Urology Torque Catheter is single lumen, torqueable catheter that is offered with one of a variety of tip configurations, each uniquely designed to facilitate access to the urinary tract. This device is made of a bio-compatible polymer reinforced with a stainless steel braided wire with one hole at the distal tip and a luer lock hub is attached to the proximal end. The catheter may be used with a guidewire up to .038 in. diameter.

5. Intended use/ Indications for Use:

The Imager II Urology Torque Catheter is indicated for use in facilitating access to the urinary tract, either through a retrograde or antegrade route, and may be used in conjunction with a guidewire or for the infusion of radiopaque contrast material. The Imager II Urology Torque Catheter is also indicated for the infusion of gels, such as BackStop™, intended for use in the urinary tract.

6. Technological Characteristics:

The Imager™ II Urology Torque Catheters are braided torqueable catheters that facilitate access to the urinary tract through either a retrograde route or an antegrade (percutaneous) route. Once access is achieved through either route, the devices may be used to facilitate guidewire exchange or to introduce radiopaque contrast media into the urinary tract. The devices are made of a biocompatible polymer reinforced with a stainless steel braided wire with one hole at the distal tip and a connector (hub) is attached to the proximal end. The black colorant used in manufacturing the currently cleared Imager™ II Urology Torque Catheter's distal tip is being replaced due to the discontinuation of the original black colorant by the vendor.

7. Performance Data:

Verification activity has been performed on representative devices of the proposed Imager™ II Urology Torque Catheters. This evaluation demonstrates that the black colorant does not affect the performance of the device and the device still meets the pre-defined product specifications for Shaft and Tip Bond (Bond Tensile), Tensile Strength (Shaft Tensile), and Tip Tensile Strength. Furthermore, the product was evaluated to confirm that the new colorant does not introduce any new risks and does not introduce any new issues of safety or effectiveness. To support this statement, the following testing was conducted: In Vitro Cytotoxicity MEM Elution, ISO Guinea Pig Maximization Sensitization, and ISO Intracutaneous Reactivity.

8. Conclusion:

The information provided in this submission demonstrates that the proposed Imager™ II Urology Torque Catheter is substantially equivalent to the predicate device (Imager™ II Urology Torque Catheter), cleared in K102527.