DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 17, 2014

Boston Scientific Corp
Matt Beauchane
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K141344
Trade/Device Name: Expel™ Nephroureteral Drainage Stent With Twist-Loc Hub System
Expel™ Ureteral Drainage Stent System
Regulation Number: 21 CFR 876.4620
Regulation Name: Uretal Stent
Regulatory Class: Class II
Product Code: FAD
Dated: October 9, 2014
Received: October 10, 2014

Dear Matt Beauchane,

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 yours,

Herbert P. Lerner -S

for
Benjamin 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)*
K141344

Device Name
Expel™ Nephroureteral Stent System with Twist-Loc™ Hub

Indications for Use *(Describe)*
The Expel Nephroureteral Stents are delivered percutaneously and are intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent, as well as providing external drainage.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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
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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)*
K141344

Device Name
Expel™ Ureteral Stent System

Indications for Use *(Describe)*
The Expel Ureteral Stent System is delivered percutaneously and is intended to establish drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally.

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)

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510(k) Summary

Per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation One Scimed Place Maple Grove, MN 55311 USA
Contact Name and Information	Matt Beauchane Regulatory Affairs Specialist Phone: 763-494-1789 Fax: 763-494-2222 Email: matt.beauchane@bsci.com
Date Prepared	20-Aug-2014
Proprietary Names	Expel™ Nephroureteral Stent System with Twist-Loc™ Hub Expel™ Ureteral Stent System
Common Name	Ureteral Stent
Classification	Classification: Class II Regulation: 21 CFR 876.4620 Product Code: FAD Classification Panel: Gastroenterology/Urology
Predicate Device	Percuflex™ Nephroureteral Stent and Percuflex™ Ureteral Stent (K924608, 26-Jan-1994)
Intended Use / Indications for Use	**Expel™ Nephroureteral Stent System with Twist-Loc™ Hub:** The Expel Nephroureteral Stents are delivered percutaneously and are intended to establish internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent, as well as providing external drainage. --- **Expel™ Ureteral Stent System:** The Expel Ureteral Stent System is delivered percutaneously and is intended to establish drainage from the ureteropelvic junction to the bladder and stenting of the ureter for all patients in whom it is desirable to place a drain which does not extend externally.

Device Description

The Expel Nephroureteral and Ureteral Stents are single-lumen, nonvascular intervention stents inserted using percutaneous access to provide internal and/or external drainage of the ureteropelvic junction to the bladder and stenting of the ureter. They are long-term indwelling devices not to exceed 30 days in the body.

Expel Nephroureteral Stents are available in outer diameters of 8.3 and 10.3 French, with working lengths ranging from 22 to 28 cm. They contain two pigtails each containing drainage holes. The locking, proximal pigtail forms in the renal pelvis, while the distal, concentric pigtail forms in the bladder. Drainage can occur internally (from the ureteropelvic junction to the bladder) or externally (from the bladder and ureteropelvic junction to the outside of the patient). Each pigtail has an adjacent radiopaque marker band. The distal end of the stent has a tapered tip and hydrophilic coating. The locking, proximal pigtail is activated by the Twist-Loc™ hub on the proximal end of the stent.

Expel Ureteral Stents are available in outer diameters of 6.3, 8.3, and 10.3 French, with working lengths ranging from 12 to 28 cm. The distal and proximal ends of the stent contain drainage holes within concentric pigtails. The pigtails form in opposite directions, with the proximal pigtail forming in the renal pelvis, and the distal pigtail forming in the bladder. Drainage occurs through pressure differential via gravity between the body cavities.

Each pigtail has an adjacent radiopaque marker band, and the distal end of the stent has a tapered tip and hydrophilic coating. A suture is looped through the most proximal drainage hole which allows for stent adjustment or removal during placement, and the suture is removed once placement is complete.

The Expel Nephroureteral and Ureteral Stents come with the following accessories that aid device placement.

- Cannulas
- Plug/Cap
- Stabilizer
- Pigtail Straightener

Comparison of Technological Characteristics

The Expel Nephroureteral and Ureteral Stents are similar in fundamental design, function, device materials, sterilization, operating principle, intended use / indication for use and fundamental technology as the predicate device, the Percuflex™ Nephroureteral Stent and Percuflex™ Ureteral Stent. The modifications from the predicate device include:

- Modified hub designs
- New stent shaft material
- Addition of radiopaque marker bands
- Extended sizes/platforms
- Modified packaging

Performance Data

The following bench testing was conducted for design elements and performance characteristics deemed appropriate to demonstrate equivalence to the predicate device. The Expel Nephroureteral and Ureteral Stents, including packaging, met the predetermined acceptance criteria ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.

- Stent Dimensions – OD and Working Length
- Stent Shaft Tensile Strength
- RO Marker Band Tensile Strength
- Hub to Shaft Tensile Strength
- Tip Tensile Strength
- Distal Tip Robustness
- Pigtail Recovery
- Pigtail Retention/Removal Force
- Resistance to Deformation
- Kink Resistance
- Flow Recovery Post Kinking
- Resistance to Liquid Leakage - Under Pressure and During Aspiration/ Vacuum
- Stent / RO Marker Radiopacity
- MRI Compatibility
- Urine Compatibility
- Cannula / Stent Connection Force
- Cannula to Stent / Stabilizer Compatibility
- Guidewire to Stent / Cannula Compatibility
- Flexible Stiffening Cannula Hub to Shaft Tensile Strength
- Stabilizer to Flexible Stiffening Cannula Connection Force
- Coefficient of Friction
- Sterile Barrier Integrity
- Pouch Seal Strength
- Thermoformed Tray Visual
- Shelf Life
- Sterilization
- Biocompatibility

Conclusion

Boston Scientific has demonstrated that the modifications made for the Expel Nephroureteral and Ureteral Stents are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the predicate device, Percuflex™ Nephroureteral Stent and Percuflex™ Ureteral Stent.