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

October 17, 2014

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

Re: K141335
Trade/Device Name: Expel™ APD Drainage Catheter System
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: Class II
Product Code: FGE
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)*
K141335

Device Name
Expel™ Drainage Catheter APD Drainage Catheter, Expel™ Drainage Catheter with Twist-Loc™ Hub APDL Drainage Catheter, Expel™ Drainage Catheter with Twist-Loc™ Hub APDL Drainage Catheter Kit, and Expel™ Large Capacity Drainage Catheter APD Large Capacity Drainage Catheter

Indications for Use *(Describe)*
The drainage catheter is intended to provide percutaneous drainage of abscess fluid and biliary collections.

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
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."

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)*
K141335

Device Name
Expel™ Drainage Catheter with Twist-Loc™ Hub Biliary Drainage Catheter
Expel™ Drainage Catheter with Twist-Loc™ Hub Biliary Drainage Catheter Kit

Indications for Use *(Describe)*
The drainage catheter is intended to provide external and internal percutaneous drainage of the biliary system.

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
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."

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

03-Sep-2014

Proprietary Names

Single Product Configurations

Expel™ Drainage Catheter APD Drainage Catheter
Expel™ Drainage Catheter with Twist-Loc™ Hub APDL Drainage Catheter
Expel™ Large Capacity Drainage Catheter APD Large Capacity Drainage Catheter
Expel™ Drainage Catheter with Twist-Loc™ Hub Biliary Drainage Catheter

Kit Configurations

Expel™ Drainage Catheter with Twist-Loc™ Hub APDL Drainage Catheter Kit
Expel™ Drainage Catheter with Twist-Loc™ Hub Biliary Drainage Catheter Kit

Common Name

Diagnostic Biliary Catheter

Classification

Classification: Class II
Regulation: 21 CFR 876.5010
Product Code: FGE
Classification Panel: Gastroenterology/Urology

Predicate Devices	Flexima™ APD™ All Purpose Drainage Catheter Set (K944290, 08-Dec-1994) Flexima™ Biliary Drainage Catheter with RO Marker (K023870, 20-Dec-2002)
Intended Use / Indications for Use	**Expel™ Drainage Catheter APD Drainage Catheter,** **Expel™ Drainage Catheter with Twist-Loc™ Hub APDL Drainage Catheter,** **Expel™ Drainage Catheter with Twist-Loc™ Hub APDL Drainage Catheter Kit,** **Expel™ Large Capacity Drainage Catheter APD Large Capacity Drainage Catheter :** The drainage catheter is intended to provide percutaneous drainage of abscess fluid and biliary collections. **Expel™ Drainage Catheter with Twist-Loc™ Hub Biliary Drainage Catheter,** **Expel™ Drainage Catheter with Twist-Loc™ Hub Biliary Drainage Catheter Kit:** The drainage catheter is intended to provide external and internal percutaneous drainage of the biliary system.
Device Description	Expel™ drainage catheters are nonvascular intervention catheters that consist of a single lumen tube with drainage holes in the distal region and a proximal hub. The catheters are inserted using percutaneous access to provide internal and/or external drainage of fluid collections in body cavities. They can be long-term indwelling devices not to exceed 90 days in the body. Expel™ APD™, APDL, and APD Large Capacity families differentiate the available French sizes, distal shape geometries, and hub types. These families contain the widest range of products with catheter outer diameters ranging from 6 to 26 French, and working lengths ranging from 15 to 45 cm. The distal ends of the catheters contain drainage holes, an adjacent radiopaque marker band, and a tapered tip. The catheter shafts have graduation markings with numeric values and a hydrophilic coating distally. Expel™ APDL family has a distal locking pigtail and a proximal Twist-Loc™ hub. Expel™ APD™ and APD

Device Description, cont.

Large Capacity families have a distal J-tip geometry and a proximal non-locking hub.

Expel™ Biliary drainage catheters are available in outer diameters of 8 to 14 French and lengths ranging from 20 to 40 cm. The distal end of the catheter contains drainage holes within a locking pigtail, an adjacent radiopaque marker band, and a tapered tip. The catheter shaft has additional drainage holes, graduation markings and numeric values, and a hydrophilic coating distally. The distal locking pigtail is activated by the proximal Twist-Loc™ hub.

The Expel™ drainage catheters come with a variety of accessories that aid in percutaneous access, device placement, device securement, and drainage fluid management. Accessories include:

- Cannulas
- Trocars
- Connecting Tubes
- Plugs / Caps
- Pigtail Straightener
- Facial Dilators
- Guidewires
- Dressing
- Catheter Cuff
- Introducers / Needles
- Cable Ties

Comparison of Technological Characteristics

The Expel™ drainage catheter families are similar in fundamental design, function, device materials, sterilization, operating principle, intended use / indication for use and fundamental technology as the predicate devices, Flexima™ APD™ All Purpose Drainage Catheter Set and Flexima™ Biliary Drainage Catheter with RO Marker. The modifications from the predicate devices include:

- Modified hub designs
- New catheter shaft material
- Addition of length graduation markings and radiopaque (RO) 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™ drainage catheter families, including packaging, met the predetermined acceptance criteria

ensuring substantial equivalence to the predicate device. No new safety or performance issues were raised during testing.

- Catheter OD
- Catheter Shaft Tensile Strength
- RO Marker Band Tensile Strength
- Hub to Shaft Tensile Strength
- Tip Tensile Strength
- Distal Tip Robustness
- Pigtail Retention (Curl Strength) / Removal Force
- Resistance to Deformation
- Kink Resistance
- Flow Recovery Post Kinking
- Resistance to Liquid Leakage
- Alcohol Compatibility
- MRI Compatibility
- Urine and Bile Compatibility
- Accessory to Catheter Connection Force
- Cannula to Catheter Compatibility
- Guidewire to Catheter/ Accessory Compatibility
- Large Capacity Catheter to Large Capacity Connecting Tube Compatibility
- Flexible Stiffening Cannula/Dilator Hub to Shaft Tensile Strength
- Large Capacity Stiffening Dilator ID to Metal Stiffening Cannula OD Compatibility
- Large Capacity Connecting Tube Hub to Shaft Tensile Strength
- Sterile Barrier Integrity
- Pouch Seal Strength
- Thermoformed Tray Visual
- Packaging Card Visual
- Shelf Life
- Sterilization
- Biocompatibility
- Coefficient of Friction
- Radiopacity

Conclusion

Boston Scientific has demonstrated that the modifications made for the Expel™ drainage catheter families are substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principle, and intended use / indication for use as the predicate devices, Flexima™ APD™ All Purpose Drainage Catheter Set and Flexima™ Biliary Drainage Catheter with RO Marker.