November 10, 2022

Boston Scientific Corporation
Liz Johnston
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

Re: K211934
Trade/Device Name: APDL Drainage Catheter System, Flexima™ APDL Drainage Catheter System Kit, Flexima™ APDL Drainage Catheter System Kit with Dissolving Tip, Flexima™ APDL Drainage Catheter System with Dissolving Tip, Flexima™ QuickStick™ Drainage Catheter System, vanSonnenberg™ Sump Catheter System Kit, vanSonnenberg™ Sump Catheter System, vanSonnenberg™ Drainage Catheter System, Flexima™ APD™ Drainage Catheter System, Flexima™ APD™ Drainage Catheter System Kit, Flexima™ APD™ Drainage Catheter System with Dissolving Tip, Flexima™ APD™ Drainage Catheter System Kit with Dissolving Tip
Regulation Number: 21 CFR§ 876.5090
Regulation Name: Suprapubic urological catheter and accessories
Regulatory Class: II
Product Code: FFA
Dated: October 13, 2022
Received: October 14, 2022

Dear Liz Johnston:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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,

Jessica K. Nguyen -S

Jessica K. Nguyen, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211934

Device Name
APDL Drainage Catheter System, Flexima™ APDL Drainage Catheter System Kit, Flexima™ APDL Drainage Catheter System Kit with Dissolving Tip, Flexima™ APDL Drainage Catheter System with Dissolving Tip

Indications for Use *(Describe)*

To provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211934

Device Name
Flexima™ QuickStick™ Drainage Catheter System

Indications for Use *(Describe)*

To provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211934

Device Name
vanSonnenberg™ Sump Catheter System Kit,
vanSonnenberg™ Sump Catheter System

Indications for Use *(Describe)*

The vanSonnenberg™ Sump Catheter is designed for use as a percutaneously placed drain for intra-abdominal fluid collections. Such conditions include abscesses, cysts, pseudocysts, bilomas, hematomas, seromas, urinomas, or any loculated fluid collection.

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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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211934

Device Name
vanSonnenberg™ Drainage Catheter System

Indications for Use *(Describe)*

To provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection.

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211934

Device Name
Flexima™ APD™ Drainage Catheter System, Flexima™ APD™ Drainage Catheter System Kit, Flexima™ APD™ Drainage Catheter System with Dissolving Tip, Flexima™ APD™ Drainage Catheter System Kit with Dissolving Tip

Indications for Use *(Describe)*

To provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection.

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

510(K) Summary Complying with 21 CFR 807.92

I. SUBMITTER INFORMATION

Submitter Name: Boston Scientific Corporation

Submitter Address:
Three Scimed Place
Maple Grove, MN 55311-1566
USA

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Fax: 763-494-2222
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Contact person name: Liz Johnston
Date Prepared: November 10, 2022

II. DEVICE INFORMATION

Tables 1 to 4 below summarize the relevant subject device information.

Table 1: APDL Drainage Catheters

UPN	Product Description
M001271240	Flexima™ APDL Drainage Catheter System
M001271310	Flexima™ APDL Drainage Catheter System
M001271320	Flexima™ APDL Drainage Catheter System
M001275080	Flexima™ APDL Drainage Catheter System with Dissolving Tip
M001271330	Flexima™ APDL Drainage Catheter System
M001271340	Flexima™ APDL Drainage Catheter System
M001271350	Flexima™ APDL Drainage Catheter System
M001271380	Flexima™ APDL Drainage Catheter System
M001271390	Flexima™ APDL Drainage Catheter System
M001271960	Flexima™ APDL Drainage Catheter System Kit
M001271970	Flexima™ APDL Drainage Catheter System Kit
M001271980	Flexima™ APDL Drainage Catheter System Kit
M001271990	Flexima™ APDL Drainage Catheter System Kit
M001275010	Flexima™ APDL Drainage Catheter System
M001275030	Flexima™ APDL Drainage Catheter System Kit
M001275090	Flexima™ APDL Drainage Catheter System Kit with Dissolving Tip
M001281340	Flexima™ APDL Drainage Catheter System with Dissolving Tip
M001281350	Flexima™ APDL Drainage Catheter System with Dissolving Tip
M001281380	Flexima™ APDL Drainage Catheter System with Dissolving Tip
M001281390	Flexima™ APDL Drainage Catheter System with Dissolving Tip
M001245061	APDL Drainage Catheter System
M001245071	APDL Drainage Catheter System
M001245081	APDL Drainage Catheter System
M001245060	APDL Drainage Catheter System
M001245070	APDL Drainage Catheter System
M001245080	APDL Drainage Catheter System

Table 2: APD Drainage Catheters

UPN	Product Description
M001271250	Flexima™ APDTM Drainage Catheter System
M001271260	Flexima™ APDTM Drainage Catheter System
M001271270	Flexima™ APDTM Drainage Catheter System
M001275060	Flexima™ APDTM Drainage Catheter System with Dissolving Tip
M001271280	Flexima™ APDTM Drainage Catheter System
M001271290	Flexima™ APDTM Drainage Catheter System
M001271300	Flexima™ APDTM Drainage Catheter System
M001271360	Flexima™ APD™ Drainage Catheter System
M001271370	Flexima™ APD™ Drainage Catheter System
M001275070	Flexima™ APDTM Drainage Catheter System Kit with Dissolving Tip
M001281290	Flexima™ APDTM Drainage Catheter System with Dissolving Tip
M001281300	Flexima™ APDTM Drainage Catheter System with Dissolving Tip
M001281360	Flexima™ APDTM Drainage Catheter System with Dissolving Tip
M001281370	Flexima™ APDTM Drainage Catheter System with Dissolving Tip

Table 3: Flexima Quickstick Drainage Catheters

UPN	Product Description
M001271460	Flexima™ QuickStick™ Drainage Catheter System
M001271470	Flexima™ QuickStick™ Drainage Catheter System

Table4: vanSonnenberg Drainage Catheters

UPN	Product Description
M001245130	vanSonnenberg™ Drainage Catheter System
M001245140	vanSonnenberg™ Drainage Catheter System

UPN	Product Description
M001201000	vanSonnenberg™ Sump Catheter System Kit
M001201050	vanSonnenberg™ Sump Catheter System Kit
M001201060	vanSonnenberg™ Sump Catheter System Kit
M001203000	vanSonnenberg™ Sump Catheter System
M001203010	vanSonnenberg™ Sump Catheter System
M001203020	vanSonnenberg™ Sump Catheter System
M001203030	vanSonnenberg™ Sump Catheter System
M001203070	vanSonnenberg™ Sump Catheter System
M001213060	vanSonnenberg™ Sump Catheter System with Dissolving Tip
M001213070	vanSonnenberg™ Sump Catheter System with Dissolving Tip
M001273000	vanSonnenberg™ Sump Catheter System
M001273010	vanSonnenberg™ Sump Catheter System
M001273030	vanSonnenberg™ Sump Catheter System
M001273040	vanSonnenberg™ Sump Catheter System
M001273060	vanSonnenberg™ Sump Catheter System Kit
M001273070	vanSonnenberg™ Sump Catheter System Kit
M001273090	vanSonnenberg™ Sump Catheter System Kit
M001273100	vanSonnenberg™ Sump Catheter System Kit
M001273130	vanSonnenberg™ Sump Catheter System
M001273180	vanSonnenberg™ Sump Catheter System Kit
M001273190	vanSonnenberg™ Sump Catheter System Kit
M001273210	vanSonnenberg™ Sump Catheter System Kit

Table 5: Additional Device Information

Common or Usual name	Regulation Number	Regulation Name	Product Code	Product Code Name	Regulatory Class
Drainage Catheter	21 CFR Part 876.5090	Suprapubic urological catheter and accessories	FFA	Tube, Drainage, Suprapubic	II

III. PREDICATE DEVICE IDENTIFICATION

Name of Predicate Device

K924608 Hydrogel Coated Percuflex Drainage Catheters
K944290 Modified (Flexima) Hydrogel Coated Drainage Catheters

For devices that are manufactured with Flexima resin (Tecoflex), K944290 is the predicate.
For devices that are manufactured from Percuflex resin, K924608 is the appropriate predicate.

These devices are Class II 21 CFR Part 876.4620, FAD (K924608), and Part 876.5090, FFA (K944290) with subsequent product codes of FAD, FGE, LJE. Predicate devices referenced above have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

All Purpose Drainage catheters are designed to provide constant, unobstructed fluid drainage from various fluid accumulations to an external and/or internal collection sites and to ensure stability during treatment. These ends are met through the choice of drainage material and by incorporating a secure fixation method in the drainage site (internally by pig-tail or “J” style tips and externally, by means of suture or adhesive). Percutaneous placement is accomplished with radiological guidance.

The following All Purpose Drainage catheters are in scope of this submission:

- APDL Drainage Catheter System
- Flexima™ APDL Drainage Catheter System Kit
- Flexima™ APDL Drainage Catheter System Kit with Dissolving Tip
- Flexima™ APDL Drainage Catheter System with Dissolving Tip
- Flexima™ APD™ Drainage Catheter System
- Flexima™ APD™ Drainage Catheter System Kit
- Flexima™ APD™ Drainage Catheter System with Dissolving Tip
- Flexima™ APD™ Drainage Catheter System Kit with Dissolving Tip
- Flexima™ QuickStick™ Drainage Catheter System
- vanSonnenberg™ Drainage Catheter System
- vanSonnenberg™ Sump Catheter System Kit
- vanSonnenberg™ Sump Catheter System

Select Boston Scientific All Purpose Drainage catheters are coated with a hydrophilic material, Glidex™, for the reduction of surface friction during placement.

Some of these catheters are also available with a biocompatible, dissolving distal tip (Temp-Tip™). The tip’s internal diameter allows the guidewire to direct the tip for accurate catheter placement; however, soon after placement, the Temp-Tip™ material dissolves, allowing the full diameter of the catheter lumen to contribute to site drainage.

All Purpose Drainage catheters are manufactured with one of two types of resins, Flexima or Percuflex.

- Flexima is a biocompatible polyurethane (Tecoflex) known for its flexibility, strength, and kink resistance. Flexima comes in durometers ranging in Firm, Regular and Soft and uses a radiopacifier for visualization under fluoroscopy.
- Percuflex is an ELVAX™ 460, ethylene vinyl acetate (EVA) copolymer for patient comfort. This material is available in firm (white in color) and regular (blue in color) durometers. The firmer durometers provide more pushability during device placement. A radiopaque additive, bismuth subcarbonate, incorporated throughout the catheter tube also aids radiopacity and percutaneous placement.

Intended Use/Indications for Use: to provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection.

V. INDICATIONS FOR USE

Predicate and subject device Intended use and Indications for Use are the same.

Drainage Device	Indications for Use
APDL Drainage Catheter System Flexima™ APDL Drainage Catheter System Kit Flexima™ APDL Drainage Catheter System Kit with Dissolving Tip Flexima™ APDL Drainage Catheter System with Dissolving Tip Flexima™ APD™ Drainage Catheter System Flexima™ APD™ Drainage Catheter System Kit Flexima™ APD™ Drainage Catheter System with Dissolving Tip Flexima™ APD™ Drainage Catheter System Kit with Dissolving Tip Flexima™ QuickStick™ Drainage Catheter System vanSonnenberg™ Drainage Catheter System	To provide percutaneous drainage of abscess fluid, biliary, nephrostomy, urinary, pleural empyemas, lung abscesses, and mediastinal collection.
vanSonnenberg Sump Catheter System vanSonnenberg Sump Catheter System Kit	For use as a percutaneously placed drain for intra-abdominal fluid collections. Such conditions include abscesses, cysts, pseudocysts, bilomas, hematomas, seromas, urinomas, or any loculated fluid collection.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The All Purpose Drainage Catheters incorporate substantially equivalent design, function, packaging, sterilization process, materials, fundamental technology, indications for use, and operating principles as those featured in the predicate drainage devices (K924608, K944290). The difference from the legally marketed predicate device is the addition of Magnetic Resonance (MR) compatibility information to the Directions for Use.

In addition, cumulative changes were implemented since the time the predicate (K924608 and K944290) 510(k)s were cleared such as a coating surfactant change, supplier color additive compound change, and resin additive supplier change.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

In order to support the addition of Magnetic Resonance Compatibility information to the Directions for Use the following nonclinical performance testing was performed:

- Radio Frequency Heating
- Force Measurement
- Image Artifact

FDA guidance "*Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environmen*t," issued May 20, 2021, and the following standards were used to guide the generation of the non-clinical data:

Document Name	Document Number	Document Version
Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging	ASTM F2182	-11a
Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	ASTM F2052	− 14
Evaluation of MR Image Artifacts from Passive Implants	ASTM F2119	– 07

In addition, the following tests were performed to support substantial equivalence to the predicate devices:

- Simulated climatic conditioning and distribution followed by packaging integrity testing
- Accelerated and real time aging followed by packaging integrity testing
- Performance testing after aging, shipping and distribution conditions in scope of K924608 and K944290
- BET assessment as recommended in AAMI ST72:2019, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing

Cumulative changes made to the devices since the clearance of the predicate (K924608 and K944290) were supported by leveraging prior testing and providing justification to support the changes.

VIII. CONCLUSION

Based on the intended use, technological characteristics, and non-clinical performance data and justifications provided, the All Purpose Drainage Catheters are substantially equivalent to the predicate devices (K924608, K944290). The Directions for Use update with magnetic resonance compatibility information for the subject devices and cumulative changes made to the device do not raise new questions of safety or effectiveness, and the subject devices are as safe and effective as the predicate devices.