January 10, 2018

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

Re: K172929
Trade/Device Name: Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LJE
Dated: December 8, 2017
Received: December 11, 2017

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,

Benjamin R. Fisher -S

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)*
To be determined. K172929

Device Name
Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath

Indications for Use *(Describe)*
The Amplatz Type Renal Sheath is recommended for the establishment of percutaneous access.

The Amplatz Type Renal Sheath Set is recommended for the establishment of percutaneous access.

The Clear Renal Sheath is recommended for the establishment of percutaneous access.

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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SECTION 5 510(k) SUMMARY

510(k) Summary for Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath

A. Sponsor

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B. Contact

Daniel FitzDaniel
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508-683-4156
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or

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Date Prepared: 8 December 2017

C. Device Name

Trade name:	Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set, Clear Renal Sheath
Common/usual name:	Catheter, Nephrostomy
Classification Name:	None
Regulation Name:	Unclassified
Regulation Class:	II
Product Code:	LJE
Panel:	Gastroenterology/Urology

D. Predicate Device

Trade name:	Ultraxx™ Nephrostomy Balloon Set
Common/usual name:	Catheter, Nephrostomy
Classification Name:	LJE – Catheter, Nephrostomy

Premarket Notification: K024050, February 27, 2003
Ultraxx™ Nephrostomy Balloon Set (formerly Cook Nephrostomy Balloon Dilation Catheter Set, Cook Urological, Inc., Spencer, IN)

E. Device Description

Amplatz Type Renal Sheaths

SECTION 5 510(k) SUMMARY

The Amplatz Type Renal Sheaths are manufactured from extruded tubing and are available in 17cm lengths with the following interior diameters in French units (F): 14F, 16F, 18F, 20F, 22F, 24F, 26F, 28F and 30F. A 20cm length renal sheath with a 30F interior diameter is also available. The Amplatz Type Renal Sheaths are constructed of blue PTFE (polytetrafluoroethylene) material, which is bismuth loaded for fluoroscopy. The tip is designed for atraumatic placement and ease of advancement over dilators or balloons.

Amplatz Type Renal Sheath Set
The Amplatz Type Renal Sheath Set includes four 17cm length (single) Amplatz Type Renal Sheaths (offered in sizes: 24F, 26F, 28F and 30 F). There are no differences between the renal sheaths offered in the Amplatz Type Renal Sheath Set and the abovementioned Amplatz Type Renal Sheaths. Aside from the renal sheaths, the Amplatz Type Renal Sheath Set contains no additional components.

Clear Renal Sheath
The Clear Renal Sheath is a 30F, 17 cm length sheath with a guidewire notch at the proximal end and a radiopaque marker at the distal tip. Renal sheaths are used to establish percutaneous access for instrumentation.

F. Intended Use
Amplatz Type Renal Sheath and Amplatz Type Renal Sheath Set
The Amplatz Type Renal Sheath is recommended for the establishment of percutaneous access.

Clear Renal Sheath
The Clear Renal Sheath is recommended for the establishment of percutaneous access.

G. Indications for Use
Same as Intended Use.

H. Technological Characteristics
The Amplatz Type Renal Sheaths and Amplatz Type Renal Sheath Set consist of an extruded tube (made of radiopaque PTFE) that has a tapered tip designed for atraumatic placement and ease of advancement over dilators or balloons.

The Clear Renal Sheath consists of an extruded tube made of clear polyvinyl chloride with a guide-wire notch at the proximal end and a radiopaque marker at the distal tip. The Clear Renal Sheath has a tapered tip designed for atraumatic placement and ease of advancement over dilators or balloons.

I. Substantial Equivalence
A direct comparison of key characteristics has been performed and demonstrates that the proposed Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath are substantially equivalent to the predicate device in terms of intended use,

technological characteristics, method of sterilization and performance characteristics. The proposed Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath are as safe and effective as the predicate device.

J. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with representative samples of the Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath.

The performance testing included:

- Sheath Length
- Sheath Outer Diameter
- Sheath Distal Tip Shape
- Sheath Distal Tip Inner Diameter
- Sheath Inner Diameter
- Sheath Proximal End OD Edge
- Guidewire Compatibility *(Clear Renal Sheath only)*
- Radiopaque Marker Location *(Clear Renal Sheath only)*
- Compression Strength *(Clear Renal Sheath only)*

The proposed Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath were evaluated in accordance with EN ISO 10993-1: 2009. The following tests were performed on the devices: MEM Elution Cytotoxicity, Guinea Pig Maximization Sensitization, Intracutaneous Reactivity and Acute Systemic Injection.

All testing performed met requirements. The proposed Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath are considered safe and effective for their intended use.

Conclusion

The information provided in this submission demonstrate that the proposed Amplatz Type Renal Sheaths, Amplatz Type Renal Sheath Set and Clear Renal Sheath are substantially equivalent to the renal sheath which is a kit component in the Ultraxx™ Nephrostomy Balloon Set cleared in K024050.