DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 5, 2016

C.R. Bard, Inc.
% Dave Yungvirt
Official Correspondent
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K160861
Trade/Device Name: Proxis™ Ureteral Access Sheath
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: FED
Dated: December 16, 2015
Received: March 29, 2016

Dear Dave Yungvirt,

This letter corrects our substantially equivalent letter of March 31, 2016.

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" (21CFR 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 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Proxis™ Ureteral Access Sheath

Indications for Use *(Describe)*
The Proxis™ ureteral access sheath is indicated for use in endoscopic urology procedures where ureteral dilation and ureteral access is desired for injection of fluids and insertion and removal of endoscopes and related instruments.

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.

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Bard Medical Division
C. R. Bard, Inc.
8195 Industrial Blvd.
Covington, GA 30014

510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Proxis™ Ureteral Access Sheath 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor:
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Contact:
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Bard Medical Division
Ph: 770-784-6414
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Submission Date: March 24, 2016

Subject Device:
Trade Name: Proxis™ Ureteral Access Sheath
Common Name: Ureteral Access Sheath
Classification Name: Endoscopic Overtube
Regulation: 21 CFR §876.1500
Regulatory Classification: II
Product Code**:** FED

Predicate Device: Legally marketed device to which substantial equivalence is claimed

- Boston Scientific Navigator™ HD Ureteral Access Sheath Set, K122649

Device Description

Proxis™ Ureteral Access Sheath is a two component ureteral dilation system which contains 1) a sheath with a lumen for passage of endoscopes and related instruments and 2) a dilator with a lumen for passage over a guidewire and injection of fluids.

Proxis™ Ureteral Access Sheath is a hydrophilic-coated sheath tube comprised of a coil reinforced polymer with a PTFE liner and marker band near the distal end. On the proximal end of the sheath is a plastic hub which provides identification for the device and acts as an interface for introducing

endoscopes and related instruments through the sheath. The dilator is comprised of a hydrophilic-coated polymer tube with a tapered distal end and a female luer connector with a lock mechanism on the proximal end to attach and lock to the hub on the sheath. The device will be offered in multiple sizes to accommodate different patient anatomies. The product is ethylene oxide sterilized (per ISO 11135:2014, *Sterilization of health care products – ethylene oxide – Requirements for development, validation and routine control of a sterilized process for medical devices*). The device is for single use.

Indications for Use

The Proxis™ ureteral access sheath is indicated for use in endoscopic urology procedures where ureteral dilation and ureteral access is desired for injection of fluids and insertion and removal of endoscopes and related instruments.

Technological Characteristics

The Proxis™ Ureteral Access Sheath has similar technological characteristics as the predicate device, Navigator™ HD Ureteral Access Sheath Set. The subject and predicate devices are based on the following technological elements:

- Similar indications for use
- Similar design features
- Provided sterile for single-use
- Composed of biocompatible materials

Performance Data

Nonclinical performance testing (bench) of the proposed device was conducted per the applicable requirements of:

- BS EN 1616:1997 + A1:1999 Sterile urethral catheters for single use
- ISO 594-2 Second Edition: 1998 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2: Lock fittings
- JIS T 3260:2012 Dilators

Additional testing was completed to compare additional performance characteristics of the subject and predicate devices.

Nonclinical biocompatibility testing was conducted in accordance with ISO 10993-1:2009, *Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and FDA Bluebook Memorandum G95-1, Use of International Standard ISO 10993 “Biological Evaluation of Medical Devices Part 1: Evaluation of Testing”.

Conclusion

The Bard Proxis™ Ureteral Access Sheath is substantially equivalent to the legally marketed predicate device as demonstrated by similar indications for use and similar design features, and nonclinical test data demonstrates that the subject device is safe and effective.