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

January 27, 2017

Cook Incorporated
Jamie Ridner
Regulatory Affairs Team Lead
750 Daniels Way
Bloomington, IN 47404

Re: K161236
Trade/Device Name: Universa Firm Ureteral Stents and Stent Sets
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: December 13, 2016
Received: December 14, 2016

Dear Jamie Ridner,

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161236

Device Name
Universa® Firm Ureteral Stents and Stent Sets

Indications for Use *(Describe)*
The Universa® Firm Ureteral Stents and Stent Sets are intended for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. The stents may be placed using endoscopic, percutaneous, or open surgical techniques.

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.

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2. 510(k) Summary

Universa® Firm Ureteral Stents and Stent Sets

21 CFR §876.4620

Date Prepared: April 29, 2016

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact Name:	Jamie Ridner
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	Phone: (812) 339-2235 x102834
Contact Fax Number:	Fax: (812) 332-0281

Device Information:

Trade Name:	**Universa® Firm Ureteral Stents and Stent Sets**
Common Name:	Stent, Ureteral
Classification Regulation:	21 CFR §876.4620
Device Class:	Class II
Product Code:	FAD
Classification Panel:	Gastroenterology/Urology Devices

Predicate Device:

The predicate devices are:

- Universa® Soft Ureteral Stents and Stent Sets cleared under 510(k) K151051 on January 11, 2016
- Bard® InLayOptima™ Ureteral Stent with Suture cleared under 510(k) K043193 on December 07, 2004

Device Description:

The Universa® Firm Ureteral Stents and Stent Sets are sterile, single-use devices. The stents are available in 5.0 to 8.0 French (Fr) diameter, with lengths ranging from 18.0 to 32.0 centimeters (cm). The stents are constructed of radiopaque polycarbonate-based polyurethane material and include a hydrophilic coating. Sideports extend along the body of the stent as well as on the pigtails to provide drainage. The stents are secured in the urinary tract with pigtail loops on the proximal and distal ends. A braided or monofilament tether for repositioning and removal of the device is located on the proximal pigtail (bladder end) of the stent. Along the stent are graduation marks to provide visualization during stent advancement and placement. The Universa® Firm Ureteral Stent includes a pigtail straightener, a small polymer tube to aid in placement over a wire guide. The pigtail straightener is removed prior to use. The stent and

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pigtail straightener can be sold as a set with a stent positioner and stainless steel wire guide. The positioner and the wire guide are available for sale separately. The Universa® Firm Ureteral Stents and Stent Sets are labeled for a 12-month indwell time; however, the tether should be removed after 14 days.

Intended Use:

The Universa® Firm Ureteral Stents and Stent Sets are intended for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. The stents may be placed using endoscopic, percutaneous, or open surgical techniques.

Comparison to Predicate Device:

The Universa® Firm Ureteral Stents and Stent Sets are similar in design and functional characteristics to the predicate devices Universa® Soft Ureteral Stents and Stent Sets (K151051) and Bard® InLayOptima™ Ureteral Stent with Suture (K043193). The characteristic differences from the proposed device and the predicate devices are pigtail curl diameter and stent material.

Test Data:

The Universa® Firm Ureteral Stents and Stent Sets were subjected to the following tests to assure design and performance under the specified testing parameters:

- Sterility
- Packaging
- Biocompatibility
- Ink Adherence
- Curl Retention Strength
- Break Strength/Tensile Strength
- Dynamic Friction/Coefficient of Friction
- Flow Rate
- MRI Testing
- Radiopacity

Conclusion:

The results of the testing provide reasonable assurance that the Universa® Firm Ureteral Stents and Stent Sets have been designed such that they it will function as intended. The proposed devices do not raise new questions of safety or effectiveness as compared to the predicate devices.