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 11, 2016

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

Re: K151051
Trade/Device Name: Universa Soft Ureteral Stents and Stent Sets
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: December 10, 2015
Received: December 11, 2015

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)*
K151051

Device Name
Universa™ Soft Ureteral Stents and Stent Sets

Indications for Use *(Describe)*
Used 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(k) Summary

Cook Incorporated
Universa™ Soft Ureteral Stents and Stent Sets
510(k) Summary
21 CFR § 807.92
Date Prepared: December 10, 2015

Submitter Information

Applicant:	Cook Incorporated (Cook)
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Fax Number:	(812) 332-0281
Contact:	Jamie Ridner
Contact Address:	Cook Incorporated 750 Daniels Way P.O. Box 489 Bloomington, IN 47402
Contact Phone Number:	(812) 339-2235 ext. 102834
Contact Fax Number:	(812) 332-0281

1. Device Information

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

2. Predicate Devices:

- AQ Hydrophilic Stents (Cook Inc., K961446)
- Bard® InLayOptima™ Ureteral Stent with Suture (C. R. Bard, Inc., K043193)

3. Comparison to Predicate:

The technological characteristics of the Universa™ Soft Ureteral Stents and Stent Sets are substantially equivalent to the predicate AQ Hydrophilic Stents in regards to intended use, design, materials, and construction.

The Universa™ Soft Stents and Stent Sets are substantially equivalent to the Bard® InLayOptima™ Ureteral Stent in regards to intended use, basic design, and function.

4. Device Description

The Universa™ Soft Ureteral Stents and Stent Sets are flexible, tubular double pigtail stents composed of radiopaque polyurethane. The devices may include a positioner with a radiopaque band, a pigtail straightener, or a wire guide. Alternatively, these sets may include only a positioner and a pigtail straightener. The Universa™ Soft Ureteral Stents and Stent Sets are 5.0 to 8.0 Fr in diameter and from 8.0 to 30.0 cm in specified length. The stents are also available in expandable multi-length versions, with diameters of 5.0 to 8.0 Fr and can accommodate ureter lengths ranging from 22.0 to 32.0 cm.

5. Intended Use

The Universa™ Soft Ureteral Stents and Stent Sets are used 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.

6. Technological Characteristics

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

1. Tensile testing (tether)
2. Break strength of stent
3. Biocompatibility testing
4. Curl retention testing (pigtails)
5. Flow rate testing
6. Ink adherence testing
7. Dynamic frictional force testing
8. Radiopacity testing
9. MRI testing

In conclusion, the results of these tests support a determination of substantial equivalence to the predicate devices, the AQ Hydrophilic Stents (Cook Inc., K961446) and the Bard® InLayOptima™ Ureteral Stent with Suture (C. R. Bard, Inc., K043193).