DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 24, 2017

Cook Incorporated
Minjin Choi
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K162104
Trade/Device Name: C-Flex Ureteral Stent Sets
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: March 17, 2017
Received: March 20, 2017

Dear Minjin Choi:

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. 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); 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,

Charles Viviano -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)*
K162104

Device Name
C-Flex Ureteral Stent Sets

Indications for Use *(Describe)*
The C-Flex Ureteral 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.
The 3.7 French C-Flex stents are indicated for pediatric patients.

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.

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

2.0 510(k) Summary

C-Flex® Ureteral Stent Set
21 CFR §807.92
Date Prepared: April 21, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Minjin Choi
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x104901
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	**C-Flex® Ureteral Stent Set**
Common Name:	Stent, Ureteral
Classification Name:	Ureteral Stent
Classification Regulation:	21 CFR §876.4620, Product Code FAD
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Device:

- Primary predicate device:
  Universa™ Soft Ureteral Stents and Stent Sets (K151051).
- Secondary predicate device:
  Bioteq® Double Pigtail Ureteral Stent Set (K033210).

Device Description:

The C-Flex Ureteral Stents are single-lumen, ureteral stents inserted using endoscopic, percutaneous, or open surgical techniques in order to provide temporary internal drainage from the ureteropelvic junction to the bladder. They are long-term indwelling devices not to exceed 6 months in the body.

The C-Flex® Ureteral Stent Set is comprised of a stent, positioner, wire guide, and catheter. The C-Flex stent is constructed from a radiopaque C-Flex material and ranges from 3.7 to 5.0 French in outer diameters with working lengths of 6.0 to 32.0 cm. The stents are available in either specified-length or multi-length stent configurations.

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

The sets will be supplied sterile and are intended for one-time use. The sets are packaged in a peel-open pouch with a three-year shelf life.

Indications for Use:

The C-Flex® Ureteral 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.
The 3.7 French C-Flex stents are indicated for pediatric patients.

Comparison to Predicate Device:

The C-Flex® Ureteral Stent Set and its primary predicate device, the Universa Soft Ureteral Stents and Stent Sets (K151051), are substantially equivalent in that these devices have similar indications for use, methods of operation, designs, and fundamental technological characteristics. The modifications from the predicate device include:

- Extended stent sizes
- Stent material
- Additional accessories

The proposed C-Flex® Ureteral Stent Set is also similar in indications for use, dimensions, and methods of operation to the Bioteq Double Pigtail Ureteral Stent Set (K033210). Differences between the proposed device and the predicate device include:

- Extended stent sizes
- Stent material
- Additional accessories

Differences between the characteristics of the proposed device set and the predicate devices are supported by testing.

Performance Data:

The following testing was performed in order to demonstrate that the proposed C-Flex® Ureteral Stent Set met applicable design and performance requirements.

- Retention Strength and Break Strength – Retention strength testing shows the curl retention during proper clinical use should retain the C-Flex Ureteral Stent Set within the intended anatomy. Testing also shows the curl retention strength must allow for removal of the C-Flex Ureteral Stent Set from the intended anatomy. Break strength testing shows the tensile force during proper clinical use should not fracture the C-Flex Ureteral Stent Set. Additional retention strength and break strength tests were conducted following a 30-day artificial urine soak after

COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

accelerated aging to the equivalence of three years both with and without a 30-day urine soak. All predetermined acceptance criteria were met.

- Gravity Flow Rate – Testing characterized the gravity flow rate of the C-Flex Ureteral Stent Set. The evaluation was conducted on the stents at time zero.
- Radiopacity – Testing assessed the radiopacity of the C-Flex Ureteral Stent Set by subjecting it to a comparative fluoroscopic evaluation. Testing was conducted on the stents at time zero.
- Biocompatibility – Testing shows that the proposed device sets conform with the biocompatibility requirements based on its intended use. All predetermined acceptance criteria were met.
- Magnetic Resonance (MR) – Testing shows that the proposed device sets are MR conditional based on defined, tested conditions. All predetermined acceptance criteria were met.

Conclusion:

The results of these tests support a conclusion that the C-Flex® Ureteral Stent Set will perform as intended. The proposed device sets do not raise new questions of safety or effectiveness as compared to the predicate devices.