September 13, 2018

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

Re: K180053
Trade/Device Name: Sof-Flex® Ureteral Stent Set
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: FAD
Dated: August 13, 2018
Received: August 14, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Mark R. Kreitz -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)*

K180053

Device Name

Sof-Flex® Ureteral Stent Set

Indications for Use *(Describe)*

The Sof-Flex Ureteral Stent Set is intended for temporary internal drainage from the ureteropelvic junction to the bladder. Sof-Flex ureteral stents have been employed to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. These stents may be placed using endoscopic, percutaneous, or open surgical techniques.

The 3 French 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.

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2.0 510(k) Summary

Sof-Flex® Ureteral Stent Set

21 CFR §807.92

Date Prepared: January 05, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Minjin Choi
Secondary Contact:	Andrew Breidenbach
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Primary Contact Phone:	(812) 335-3575 x104901
Contact Fax:	(812) 332-0281

Device Information:

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

Predicate Devices:

- Primary predicate device:

  Universa™ Soft Ureteral Stents and Stent Sets (K151051)

- Secondary predicate device:

  C-Flex® Ureteral Stent Set (K162104)

Reference Device:

- Kwart Retro-Inject Ureteral Stent (K162109)

Device Description:

The Sof-Flex Ureteral Stent is a single-lumen ureteral stent indicated for endoscopic, percutaneous, or open surgical techniques in order to provide temporary internal drainage from the ureteropelvic junction to the bladder. This ureteral stent is a long-term indwelling device not to exceed 6 months in the body.

The Sof-Flex Ureteral Stent Set is composed of a Sof-Flex Ureteral Stent, positioner, and wire guide. The Sof-Flex Ureteral Stents may be sold in sets or as standalone devices.

The Sof-Flex stent is constructed from radiopaque polyurethane and is available in multiple sizes. The stent sizes range from 3 to 12 Fr in outer diameter with a length between 4 to 32 cm. The stents are available in a specified-length or multi-length configuration.

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

Indications for Use:

The Sof-Flex Ureteral Stent Set is intended for temporary internal drainage from the ureteropelvic junction to the bladder. Sof-Flex ureteral stents have been employed to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. These stents may be placed using endoscopic, percutaneous, or open surgical techniques. The 3 French stents are indicated for pediatric patients.

Comparison to Predicate Devices:

The Sof-Flex Ureteral Stent Set and the primary predicate device, Universa Soft Ureteral Stents and Stent Sets (K151051), are substantially equivalent in that they have an identical intended use. Furthermore, the devices have a similar method of operation, design, and dimensions. The Universa Soft Ureteral Stent Set (K151051) was chosen as the primary predicate device because it shares the most similar indications for use and technological characteristics to the device under review. The modifications from the predicate device includes:

- Indication for Use
- Stent Dimensions

- Stent Material

The Sof-Flex Ureteral Stent Set also has an identical intended use to the secondary predicate device, C-Flex Ureteral Stent Set (K162104). Furthermore, the devices have a similar method of operation, design, dimensions, and pediatric indications. This secondary predicate device was used to support the pediatric indications and dimensions of the 3 Fr. Sof-Flex stents. Modifications between the subject device and the predicate device include:

- Indication for Use
- Stent Dimensions
- Stent Material

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

Technological Characteristics:

The subject device, Sof-Flex Ureteral Stent Set, was subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

Performance Testing:

- Tensile Strength and Retention Strength Testing (Time Zero and Aged) – The retention strength shall be ≥ 0.03 N but ≤ 3.9 N. The minimum break strength shall be > 3.9 N. The acceptance criteria were met.
- Flow Rate (Time Zero) – Gravity flow rate measurements were performed for characterization purposes only and therefore there was no acceptance criteria.
- Radiopacity Testing (Time Zero) – The radiopacity of the subject device was evaluated by subjecting it to a comparative fluoroscopic evaluation and performed in accordance with ASTM F640-12. The acceptance criterion was met.
- Magnetic Resonance (MR) Imaging Safety Testing – Performed in accordance with ASTM F2503-13, ASTM F2052-14, ASTM F2213-06(2011), and ASTM F2119-07(2013)

Biocompatibility Testing:

- Per ISO 10993-1(2009) and FDA guidance for cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, material-mediated pyrogenicity,

subacute/subchronic toxicity, genotoxicity, chronic toxicity, and implantation were performed to ensure the biocompatibility of the subject device set.

- A reference device, Kwart Retro-Inject Ureteral Stent (K162109), has identical stent configurations (specified- and multi-length) and similar stent materials as some of the subject device configurations. Comparative leachable studies of the Sof-Flex Ureteral Stent and Kwart Retro-Inject Ureteral Stent were presented to support the toxicological equivalence of the subject and reference devices.

Conclusion:

All predetermined acceptance criteria for the testing were met. Therefore, the results of these tests support a conclusion that the Sof-Flex Ureteral Stent will perform as intended and support a determination of substantial equivalence to the predicate devices.