November 23, 2018

Cook Incorporated
Yuan Zhou
Regulatory Affairs Team Lead
750 Daniels Way
Bloomington, Indiana 47404

Re: K180557
Trade/Device Name: Greene Renal Transplant Stent Set
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: October 23, 2018
Received: October 24, 2018

Dear Yuan Zhou:

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); 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,

Glenn B. Bell -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180557

Device Name
Greene Renal Transplant Stent Set

Indications for Use *(Describe)*
Greene Renal Transplant Stent Set is used to establish temporary internal drainage from the ureteropelvic junction to the bladder. It is indicated for use following renal transplant.

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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Greene Renal Transplant Stent Set
21 CFR §807.92
Date Prepared: October 17, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Yuan Zhou Karthik Pillai
Contact Phone Number:	(812) 335-3575 x102529
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Greene Renal Transplant Stent Set**
Common Name:	Ureteral stent
Classification Name:	Ureteral stent
Classification Regulation:	21 CFR §876.4620
Product Code:	FAD
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Devices:

- K961446 AQ Hydrophilic Stent (Cook Urological).

Device Description:

The Greene Renal Transplant Stent Set is sterile, single-use device. The Greene Renal Transplant Stent Set is comprised of a double pigtail multi-length silicone stent, a radiopaque polyurethane ureteral catheter, a vinyl stent positioner and a stainless steel wire guide. The stent is available in sizes, 6.0 and 7.0 Fr with multi-length 8 to 20 centimeters. The stents are constructed of radiopaque silicone elastomer. Sideports extend along the body of the stent as well as on the curled pigtail loops (pigtail) to provide drainage. The stents are secured in the urinary tract with pigtail loops on the proximal and distal ends. There are black ink markings at the proximal and distal ends, and grey ink marks on the stent body which provide visualization during stent

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advancement and placement. The Greene Renal Transplant Stent is labeled for a 3-month indwell time.

The set will be supplied sterilized by ethylene oxide gas in a peel-open package and intended for one-time use. The product is packaged with three-year shelf life.

Intended Use:
Greene Renal Transplant Stent Set is used to establish temporary internal drainage from the ureteropelvic junction to the bladder. It is indicated for use following renal transplant.

Comparison to Predicate Devices:
The Greene Renal Transplant Stent Set and the predicate device, AQ Hydrophilic Stents (K961446) are substantially equivalent in that these devices are similar in intended use, methods of operation, designs, and fundamental technological. The differences between the subject device and the predicate device do not raise new issues of the safety and effectiveness as the subject device has undergone clinically relevant performance and biocompatibility testing to ensure the reliability of the subject device.

Performance Data:
The following tests have been conducted to ensure reliable design and performance under the specified testing parameters. The Greene Renal Transplant Stent Set was subjected to the tests. These tests include:

- Sterility
- Packaging
- Biocompatibility
- Stent Radiopacity Test
- Stent Dimensional Test
- Stent Curl Retention Test
- Stent Kink Radius Test
- Stent Simulated Use Test
- Stent Flow Rate and Lumen Blockage Test
- Stent MRI Compatibility Test
- Stent Retention and Tensile Test
- Catheter Radiopacity Test
- Catheter Leakage and Lumen Blockage Test
- Catheter Kink Radius Test
- Catheter Tensile Strength Test

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Conclusion:

The results of these tests provide reasonable assurance that the Greene Renal Transplant Ureteral Stent Set met the design input requirements based on the intended use. The subject device does not raise new questions of safety or effectiveness as compared to the predicate.