February 23, 2018

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

Re: K171601
Trade/Device Name: Ultraxx™ Nephrostomy Balloon Catheter
Regulatory Class: Unclassified
Product Code: LJE
Dated: January 17, 2018
Received: January 18, 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. 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.

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.

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,

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)*

K171601

Device Name

Ultraxx™ Nephrostomy Balloon Catheter

Indications for Use *(Describe)*

The Ultraxx™ Nephrostomy Balloon Catheter is used to dilate the musculofascial tract, renal capsule, and parenchyma to establish and maintain a percutaneous tract.

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

Ultraxx™ Nephrostomy Balloon Catheter

21 CFR §807.92

Date Prepared: May 31, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Minjin Choi
	Andrew Breidenbach
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:	**Ultraxx™ Nephrostomy Balloon Catheter**
Common Name:	Catheter, Nephrostomy
Classification Regulation:	None, Product Code LJE
Device Class/Classification Panel:	Unclassified, Gastroenterology/Urology

Predicate Device:

- Primary predicate device:

  NephroMax™ High Pressure Nephrostomy Balloon Catheter (K121614)

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- Secondary predicate device:

Cook Nephrostomy Balloon Dilation Catheter Set (K024050)

Device Description:

The Ultraxx™ Nephrostomy Balloon Catheter is used to dilate the musculofascial tract, renal capsule, and parenchyma to establish and maintain a percutaneous tract. The main components of the subject device set include the Ultraxx™ Nephrostomy Balloon Catheter (Ultraxx catheter) and Amplatz sheath. The patient-contacting materials of this set include the Amplatz sheath and Ultraxx catheter's balloon, catheter tubing, marker band, and adhesive.

The Ultraxx catheter has a dual lumen shaft with a dilatation balloon on its distal end. One of the lumens accepts a wire guide, and the other is used to inflate the balloon. The catheter material is constructed from a polyether block polyamide copolymer and is available in an outer diameter of 6 Fr with a length of 55 cm. The balloon of the catheter is constructed from polyethylene terephthalate (PET) and is available in nominal inflated outer diameters of 6 to 10 mm with a length of 15 cm. A platinum radiopaque marker band is positioned on the distal end of the balloon catheter which confirms accurate placement of the catheter. The maximum rated balloon pressure is 20 atm.

The Amplatz sheath is available in either polytetrafluoroethylene (PTFE) or a clear polyvinyl chloride (PVC). Both types of sheaths are available in inner diameters ranging from 18 to 32 Fr with a working length of 17 cm. The distal end has a smoothly rounded beveled tip for ease of insertion. The proximal end has a guidewire notch which functions to secure the wire guide and keep it out of the way during a nephrostomy procedure.

The Ultraxx™ Nephrostomy Balloon Catheter is a short-term use device, sterilized by ethylene oxide, and intended for one-time use. The set is packaged in a peel-open pouch with a three-year shelf life.

Indications for Use:

The Ultraxx Nephrostomy Balloon is used to dilate the musculofascial tract, renal capsule, and parenchyma to establish and maintain a percutaneous tract.

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Comparison to Predicate Devices:

The Ultraxx Nephrostomy Balloon Catheter and the primary predicate device, NephroMax High Pressure Nephrostomy Balloon Catheter (K121614) are substantially equivalent in that these devices have similar intended uses, designs, dimensions, and methods of operation. The subject device and secondary predicate device, the Cook Nephrostomy Balloon Dilation Catheter Set (K024050) are also similar in intended uses, designs, materials, and methods of operation. The modifications from the predicate device include:

- Indication for Use
- Balloon Catheter Size
- Balloon Catheter Material

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

Performance Data:

The following testing was performed in order to demonstrate that the subject device, Ultraxx Nephrostomy Balloon Catheter met applicable design and performance requirements.

- Biocompatibility
- Balloon Rated Burst Pressure, Compliance (pressure-diameter relationship characterization), and Deflation Time
- Tensile Testing of Balloon and Sheath Components, Joints and Bonds
- Balloon Protector Removal Force
- Radiopaque Marker Band Location and Radiopacity Verification
- Component Compatibility and Dimensional Verification
- Shelf Life of Three Years Accelerated Aging

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Conclusion:

All predetermined acceptance criteria of the testing were met. Therefore, the results of these tests support a conclusion that the Ultraxx Nephrostomy Balloon Catheter will perform as intended and support a determination of substantial equivalence to the predicate devices.