March 27, 2019

Cook Incorporated
Paul Meyer
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K181735
Trade/Device Name: Percutaneous Neonatal Pigtail Nephrostomy Set, Pediatric Nephrostomy Stent Set
Regulatory Class: Unclassified
Product Code: LJE
Dated: February 18, 2019
Received: February 19, 2019

Dear Paul Meyer:

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. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] 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) 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,

Angel A. Soler-garcia -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)*
K181735

Device Name
Percutaneous Neonatal Pigtail Nephrostomy Set

Indications for Use *(Describe)*
This device is intended for percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy drainage in neonatal 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K181735

Device Name
Pediatric Nephrostomy Stent Set

Indications for Use *(Describe)*
This device is used as a nephrostomy drainage catheter and ureteral stent in pediatric patients 2 years and older.

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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510(k) Summary

Percutaneous Neonatal Pigtail Nephrostomy Set and
Pediatric Nephrostomy Stent Set
21 CFR §807.92
Date Prepared: February 18, 2019

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Paul Meyer
Secondary Contact:	Andrew Breidenbach
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Primary Contact Phone:	(812) 335-3575 x105299
Secondary Contact Phone:	(812) 335-3575 x105147
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Percutaneous Neonatal Pigtail Nephrostomy Set Pediatric Nephrostomy Stent Set
Common Name:	Catheter, Nephrostomy
Classification Name:	None
Classification Regulation:	None
Product Code:	LJE
Device Class/Classification Panel:	Unclassified, Gastroenterology/Urology

Predicate Device:

The predicate device is the Universa Percutaneous Drainage Catheter cleared under 510(k) Premarket Notification number K140085. The secondary predicate is Angiomed's Pediatric Percutaneous Nephrostomy Set cleared under K854909.

Device Description:

The Percutaneous Neonatal Pigtail Nephrostomy Set comprises a 6.0 French (Fr) pigtail drainage catheter, a 22-gauge trocar needle, an 18-gauge trocar needle, a 5.0-Fr dilator, a 6.0-Fr dilator, a 7.0-Fr dilator, a retention disc and pull tie, a 10-Fr connecting tube, and a 0.038-inch (in) diameter, 30-centimeter (cm) wire guide.

The Pediatric Nephrostomy Stent Set comprises an 8.2-Fr pigtail drainage catheter with 4.7-Fr stent tubing, a retention disc and pull tie, and 10-Fr connecting tube.

Indications for Use:

Percutaneous Neonatal Pigtail Nephrostomy Set

Intended for percutaneous placement of a pigtail catheter in the renal pelvis for nephrostomy drainage in neonatal patients.

Pediatric Nephrostomy Stent Set

This device is used as a nephrostomy drainage catheter and ureteral stent in pediatric patients 2 years and older.

Comparison to Predicate Device:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Differences between the subject devices and the predicate device include a difference in indications for use, patient population, dimensions, and materials. Characteristics of the subject devices that differ from the predicate device are supported by testing and analysis.

Performance Data:

The following testing was performed to demonstrate that the proposed Percutaneous Neonatal Pigtail Nephrostomy Set and Pediatric Nephrostomy Stent Set met applicable design and performance requirements.

- Sterilization
- Packaging Performance
- Biocompatibility
- Dimensional Verification
- Component Compatibility
- Curl Retention
- Leakage and Flow Rate
- Tensile Strength
- Radiopacity
- Magnetic Resonance
- Performance Verification after Accelerated Aging

Conclusion:

The results of these tests provide reasonable assurance that the Percutaneous Neonatal Pigtail Nephrostomy Set and Pediatric Nephrostomy Stent Set will function as intended. The subject devices do not raise new questions of safety and/or effectiveness as compared to the predicate device.