January 29, 2020

Cook Incorporated
Carly Powell
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K191498
Trade/Device Name: Cook-Cope Loop Nephrostomy Set
Ultrathane Nephrostomy Set with Mac-Loc
Ultrathane Suprapubic Set with Mac-Loc
Regulatory Class: Unclassified
Product Code: LJE, KOB
Dated: December 3, 2019
Received: December 4, 2019

Dear Carly Powell:

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 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica K. Nguyen, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K191498

Device Name
Cook-Cope Loop Nephrostomy Set
Ultrathane Nephrostomy Set with Mac-Loc
Ultrathane Suprapubic Set with Mac-Loc

Indications for Use *(Describe)*
Cook-Cope Loop Nephrostomy Set: This device is used for percutaneous placement of a loop catheter in the renal pelvis for nephrostomy drainage.

Ultrathane Nephrostomy Set with Mac-Loc: This device is used for percutaneous placement of a loop catheter in the renal pelvis for nephrostomy drainage.

Ultrathane Suprapubic Set with Mac-Loc: The Ultrathane Suprapubic Set with Mac-Loc is used to provide bladder drainage by percutaneous placement of a loop catheter.

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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510(k) Summary

Cook-Cope Loop Nephrostomy Set
Ultrathane® Nephrostomy Set with Mac-Loc®
Ultrathane® Suprapubic Set with Mac-Loc®
As required by 21 CFR §807.92
Date Prepared: December 3, 2019

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Carly Powell Paul Meyer
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 335-3575 x104913
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Cook-Cope Loop Nephrostomy Set Ultrathane® Nephrostomy Set with Mac-Loc® Ultrathane® Suprapubic Set with Mac-Loc®
Common Name:	Catheter, Nephrostomy (Product Code: LJE) Catheter, Suprapubic (and Accessories) (Product Code: KOB)
Classification Name:	None (Product Code: LJE), Suprapubic urological catheter and accessories (Product Code: KOB)
Regulation:	None (Product Code: LJE) 21 CFR §876.5090 (Product Code: KOB)
Device Classification:	Unclassified, Class II
Product Code, Panel:	LJE, KOB, Gastroenterology/Urology

Predicate Device:

- Primary predicate: The Universa® Percutaneous Drainage Catheter Sets cleared on November 18, 2014 (K140085).
- Secondary predicate: Dawson-Mueller Drainage Catheter and Set within the Multipurpose Drainage Catheter and Set cleared on May 1, 2018 (K173035).

Device Description:

The bundled submission includes the Cook-Cope Loop Nephrostomy Set, Ultrathane® Nephrostomy Set with Mac-Loc®, and the Ultrathane® Suprapubic Set with Mac-Loc®.

- Cook-Cope Loop Nephrostomy Set and Catheter: The catheter is placed using standard percutaneous nephrostomy techniques into the kidney. The catheter is then secured in place by pulling the suture taut to create the distal retention loop, wrapping around the catheter shaft and knotting the suture. The latex is then folded over the suture and the excess suture is cut off. The catheter is kept in place within the patient using a retention disc.
- Ultrathane Nephrostomy Set with Mac-Loc: The catheter is placed using standard percutaneous nephrostomy techniques. The catheter is then secured in place by pulling the suture taut to create the distal retention loop. While maintaining traction on the monofilament, the locking cam lever is pushed down until a distinct “snap” is felt. The catheter’s distal loop is now locked into position. The excess suture is trimmed off. The catheter is then kept in place within the patient using a retention disc.
- Ultrathane Suprapubic Set with Mac-Loc: The catheter is placed using standard suprapubic techniques. The catheter is then secured in place by pulling the suture taut to create the distal retention loop. While maintaining traction on the tether, the locking cam lever is pushed down until a distinct “snap” is felt. The catheter’s distal loop is now locked into position. The excess suture is trimmed off. The catheter is then kept in place within the patient using the enclosed StatLock device.

The subject percutaneous drainage catheter sets consist of a flexible tube with an open distal tip and drainage holes. The distal end of the subject devices has either a Mac-Loc locking loop or a cope loop. A Mac-Loc locking loop mechanism secures the distal

catheter loop configuration by means of a nylon monofilament. After the catheter is placed in the desired location, the nylon thread is pulled tight to form the distal loop configuration. Then the locking cam lever can be pushed down to snap into position, thereby locking the distal loop in position. The cope loop configuration is formed by pulling back the suture, and then the loop can be locked in place by sliding a latex sleeve over the suture.

Some catheter sets have a radiopaque marker to aid the user in placement. The proximal hub assembly of the devices provides a Luer lock hub to allow the user to connect to a fluid collection device (not subject of this submission). Accessories include introducing catheters, catheter securing devices, needles, cannulas, stylets, dilators, and wire guides.

Indications for Use:

- The Cook-Cope Loop Nephrostomy Set: This device is used for percutaneous placement of a loop catheter in the renal pelvis for nephrostomy drainage.
- The Ultrathane Nephrostomy Set with Mac-Loc: This device is used for percutaneous placement of a loop catheter in the renal pelvis for nephrostomy drainage.
- The Ultrathane Suprapubic Set with Mac-Loc: The Ultrathane Suprapubic Set with Mac-Loc is used to provide bladder drainage by percutaneous placement of a loop catheter.

Comparison to Predicates:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate devices. Differences between the subject devices and the predicate devices include slight dimensional variations and variations in materials. Characteristics of the subject devices that differ from the predicate device are supported by testing. These differences do not raise any new questions of safety and/or effectiveness.

Performance Data:

The subject devices underwent the applicable testing listed below to ensure reliable design and performance under the testing parameters. Performance and biocompatibility

testing were conducted in accordance with applicable performance standards and FDA guidance documents to confirm the reliable performance of critical device characteristics.

- Dimensional Testing
- Compatibility and post-urine compatibility
- Flow Rate and Liquid Leakage
- Tensile Strength – Hub-to-Shaft, Shaft, Catheter to Connecting Tube
- Retention
- Radiopacity
- MRI Testing
- Biocompatibility – Testing shows that the subject devices conform to the biocompatibility requirements based on its intended use. All evaluation criteria were met.
- Sterilization
- Package integrity and stability
- Shelf-life

All predetermined acceptance criteria were met.

Conclusion:

The data included in this submission indicate that the subject devices do not raise new questions of safety and/or effectiveness compared to the predicate devices (K140085) and (K173035), which supports a determination of substantial equivalence.