September 21, 2018

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

Re: K180029
Trade/Device Name: Malecot Nephrostomy Catheter/Stent Set
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD, LJE
Dated: August 24, 2018
Received: August 27, 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); 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: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K180029

Device Name
Malecot Nephrostomy Catheter/Stent Set

Indications for Use *(Describe)*
The Malecot Nephrostomy Catheter/Stent Set is intended for use as a nephrostomy drainage catheter and ureteral stent. The catheter is placed percutaneously through an existing nephrostomy 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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COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

510(k) Summary

K180029

Malecot Nephrostomy Catheter/Stent Set

21 CFR §807.92

Date Prepared: December 29, 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:	**Malecot Nephrostomy Catheter/Stent Set**
Common Name:	Stent, Ureteral
Classification Regulation:	21 CFR§876.4620, Ureteral Stent
Product Code:	FAD, LJE
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Devices:

- Primary predicate device:

  Expel Nephroureteral Drainage Stent with Twist-Loc Hub System (K141344)

- Secondary predicate device:

  Universa Malecot Drainage Catheter Exchange Set (K140085)

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Device Description:

The Malecot Nephrostomy Catheter/Stent Set consists of a catheter/stent, two flexible stylets, a connecting tube, and a retention disc with pull tie. The Malecot catheter/stent is a single device consisting of an externally draining catheter in line with an internally draining ureteral stent. It is constructed from radiopaque polyurethane and has a malecot wing design located on the distal end of the catheter and proximal end of the stent. The stent (distal) portion of the device is available in an outer diameter of 7 Fr with a length of 20 cm. The catheter (proximal) portion of the device is available in an outer diameter between 12 Fr to 24 Fr with lengths of 25.5, 27.0, or 27.4 cm.

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 Malecot Nephrostomy Catheter/Stent Catheter Set is intended for use as a nephrostomy drainage catheter and ureteral stent. The catheter is placed percutaneously through an existing nephrostomy tract.

Comparison to Predicate Devices:

The Malecot Nephrostomy Catheter/Stent Set and the primary predicate device, Expel Nephroureteral Drainage Stent with Twist-Loc Hub System (K141344), are substantially equivalent in that these devices have similar intended uses, methods of operation, and designs. The subject device and secondary predicate device, Universa Percutaneous Drainage Catheter Set (K140085) are also similar in intended uses, methods of operation, and dimensions. The modifications from the predicate devices include:

- Indications for Use
- Catheter/Stent Size
- Catheter/Stent Retention Configuration
- Catheter/Stent Materials
- Stylet

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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, Malecot Nephrostomy Catheter/Stent Set, met applicable design requirements.

- Biocompatibility
- Tensile Strength
  - Catheter and Stent Shaft
  - Hub to Shaft Bond of Catheter and Flexible Stylet
  - Malecot
  - Connection of Catheter to Connecting Tube
- Retention Strength
  - Catheter to Connecting Tube and Retention Disc
- Flow Rate and Liquid Leakage
  - Curved and Straight Flow Rate
- Radiopacity
- Component Compatibility
- Magnetic Resonance (MR) Imaging Safety
- Shelf Life following Accelerated Aging to Three-year Real-time Equivalency

Conclusion:

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