January 18, 2019

Cook Incorporated
Danlu Chen
Regulatory Affairs Specialist
750 Daniels Way, P.0. Box 489
Bloomington, IN 47402

Re: K181097
Trade/Device Name: Cook® Cystostomy Catheter Set
Regulation Number: 21 CFR§ 876.5090
Regulation Name: Suprapubic Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOB
Dated: December 19, 2018
Received: December 20, 2018

Dear Danlu Chen:

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. 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)*
K181097

Device Name
Cook® Cystostomy Catheter Set

Indications for Use *(Describe)*
The Cook® Cystostomy Catheter Set is used for temporary suprapubic urinary diversion and drainage for less than or equal to four weeks.

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

Cook® Cystostomy Catheter Set
21 CFR §876.5090
Date Prepared: January 16, 2019

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Jiayin Furnish
	Andrew Breidenbach
Applicant Address:	Cook Incorporated
	750 Daniels Way
	Bloomington, IN 47404
Contact Phone:	(812) 335-3575
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Cook® Cystostomy Catheter Set
Device Common Name:	Suprapubic Urological Catheter and Accessories
Classification Name:	Suprapubic Urological Catheter and Accessories
Regulation Number:	21 CFR §876.5090
Product Code:	KOB
Device Classification:	Class II
Review Panel:	Gastroenterology/Urology

Predicate Devices:

All Silicone Supra-Pubia Catheter, Models 4880/4890 (K014002)

Universa® Percutaneous Drainage Catheter Set (Malecot Suprapubic Set) (K140085)

Device Description:

The Cook® Cystostomy Catheter Set is composed of a single-lumen silicone catheter available in 8 to 12 French with a working length of 54 centimeters, a trocar stylet with access sheath having an outer diameter of 10 to 14 French with a length of either 11 or 11.2 centimeters, a drainage

adapter with stopcock available in 12 to 16 gauge and a soft low-profile silicone catheter support with pull tie. The set is supplied sterile, intended for one-time use only, and packaged in a peel-open pouch with a three-year shelf life.

Indications for Use:

The Cook® Cystostomy Catheter Set is used for temporary suprapubic urinary diversion and drainage for less than or equal to four weeks.

Comparison to Primary Predicate Device:

The subject device, Cook® Cystostomy Catheter Set, and the predicate device, All Silicone Supra-Pubia Catheter, Models 4880/4890 (K014002), are similar in intended uses, fundamental technological characteristics, and methods of operation. Differences between the characteristics of the subject device and the predicate device include:

- Indications for Use
- Design Features
- Dimensions

Differences between the characteristics of the subject device and the predicate device are supported by testing. The subject device raises no new questions of safety and effectiveness as compared to the predicate device.

Comparison to Secondary Predicate Device:

The subject device, Cook® Cystostomy Catheter Set, and the secondary predicate device, Universa® Percutaneous Drainage Catheter Set (Malecot Suprapubic Set) (K140085), are similar in intended uses, fundamental technological characteristics, and methods of operation. Differences between the characteristics of the subject device and the predicate device include:

- Indications for Use
- Design Features
- Dimensions

Differences between the characteristics of the subject device and the secondary predicate device are supported by testing. The subject device raises no new questions of safety and effectiveness as compared to the predicate device.

Performance Data:

The following testing was performed to demonstrate that the Cook® Cystostomy Catheter Set met applicable design requirements.

- Biocompatibility
- Tensile Strength
- Leakage and Flow
- Dimensional and Compatibility

Results of the testing support a conclusion that the subject device Cook® Cystostomy Catheter Set met the design input requirements based on the intended use and raises no new questions of safety and effectiveness as compared to the predicate device