December 26, 2018

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

Re: K182709
Trade/Device Name: One-Step Suprapubic Introducer
Regulation Number: 21 CFR 876.5090
Regulation Name: Suprapubic Urological Catheter and Accessories
Regulatory Class: Class II
Product Code: KOB
Dated: September 26, 2018
Received: September 27, 2018

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. 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 post-marketing 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)*

K182709

Device Name
One-Step Suprapubic Introducer

Indications for Use *(Describe)*
The One-Step Suprapubic Introducer is used for introducing a drainage catheter suprapubically into the bladder.

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."

COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

One-Step Suprapubic Introducer
21 CFR §876.5090
Date Prepared: December 26, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Carly Powell
Secondary Contact:	Karthik Pillai, Ph.D.
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575 x104913
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Names:	**One-Step Suprapubic Introducer**
Common Name:	Catheter, Suprapubic
Classification Name:	Suprapubic urological catheter and accessories
Regulation:	21 CFR §876.5090
Product Code:	KOB
Review Panel:	Class II, Gastroenterology/Urology

Predicate device:

The One-Step Suprapubic Introducer is substantially equivalent to the following device:

- Predicate device: Supra-Foley Suprapubic Catheter Introducer cleared under K884061

Device Description:

The One-Step Suprapubic Introducer is comprised of a stainless steel trocar stylet needle and a dilator with a peel-away sheath. The trocar stylet needle is 20 centimeters (cm) long with a trocar beveled tip at the distal end of the device. The dilator is 14-22 French (Fr) and 18-19 cm in length. The peel-away sheath is 14-22 Fr and 17 cm in length. The three components are designed to fit together to form a single assembly.

Intended Use:

The One-Step Suprapubic Introducer is intended for introducing a drainage catheter suprapubically into the bladder.

Comparison to Predicate:

The subject and predicate device, Supra-Foley Suprapubic Catheter Introducer, are substantially equivalent in that these devices are similar in indications for use and method of placement. Additionally, the subject device has a similar design and technological characteristics as the predicate device. The differences between the subject device and the predicate device include materials, dimensions, and components. Characteristics of the subject device that differ from the predicate device are supported by testing and do not raise any new questions of safety and effectiveness.

Performance Data:

The subject device, the One-Step Suprapubic Introducer, was subjected to applicable testing to assure reliable design and performance under the testing parameters. The following tests have been conducted to ensure reliable design and performance under the specified testing parameters:

- Radiopacity Testing
- Peel-Away Shaft Tensile Test
- Dilator Shaft Tensile Test
- Peel Force
- Rollback Testing
- Dilator Hub-to-Shaft Tensile Test
- Dimensional Testing
- Biocompatibility – Testing shows that the subject device conforms to the biocompatibility requirements based on its intended use. All evaluation criteria were met. The following biological effects were evaluated:
    - Cytotoxicity
    - Sensitization
    - Irritation/Intracutaneous Reactivity
    - Acute Systemic Toxicity
- Sterilization
- Package integrity and stability
- Shelf-life

All predetermined acceptance criteria were met.

Conclusion:

The data included in this submission indicate that the subject device does not raise new questions of safety or effectiveness compared to the predicate device, the Supra-Foley Suprapubic Catheter Introducer (K884061), which supports a determination of substantial equivalence.