June 28, 2018

Cook Incorporated
Chelsea Woods
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47404

Re: K181144
Trade/Device Name: Angled Tip Ureteral Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOD
Dated: April 30, 2018
Received: May 1, 2018

Dear Chelsea Woods:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

Mark R. Kreitz -S
2018.06.28 11:28:42 -04'00'

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

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

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)*

K181144

Device Name
Angled Tip Ureteral Catheter

Indications for Use *(Describe)*
These devices are intended for access and catheterization of the urinary tract, including the following applications:

- Delivery of contrast media
- Navigation of a tortuous ureter
- Access, advancement, or exchange of wire guides

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

3

2.0 510(k) Summary

Angled Tip Ureteral Catheter
21 CFR §807.92
Date Prepared: April 30, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Chelsea Woods
Secondary Contact:	Karthik Pillai
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 335-3575 x104707
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Angled Tip Ureteral Catheter
Common Name:	Urological Catheter
Classification Name:	Urological Catheter and Accessories
Classification Regulation:	21 CFR §876.5130, Product Code KOD
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Device:

- Kumpe Access Catheter (K171600)

Reference Device:

- Imager™ II Catheter (K102527)
- Renal Access Cobra Catheter (K171600)
- Ureteral Catheter (K171662)

Device Description:

The Angled Tip Ureteral Catheter is constructed from polyurethane tubing and is designed with a female Luer lock adapter. The catheter is available in 5 and 6 French diameters and a length of 70 centimeters. The distal tip of the catheter has an angle of 20°, sideports, and a taper. The female Luer lock adapter is constructed from polyamide. The subject device

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

also includes a stainless steel wire guide coated with PTFE. The wire guide diameter is 0.035 inches and the length is 145 centimeters

Indications for Use:

These devices are intended for access and catheterization of the urinary tract, including the following applications:

- Delivery of contrast media
- Navigation of a tortuous ureter
- Access, advancement, or exchange of wire guides

Comparison to Predicate Device:

The subject device has the same indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Differences between the subject device and the predicate device include design and materials. Characteristics of the subject device that differ from the predicate device are supported by testing and analysis.

Performance Data:

The following testing was performed at time-zero and following accelerated aging in order to demonstrate that the subject device Angled Tip Ureteral Catheter met applicable design and performance requirements.

- Biocompatibility
- Sterilization
- Dimensional and Compatibility
- Radiopacity
- Kink Radius
- Tensile
- Blockage and leakage

Conclusion:

The results of these tests support a conclusion that the Angled Tip Ureteral Catheter will perform as intended. The subject device does not raise new questions of safety and/or effectiveness when compared to the predicate device.