September 14, 2018

Cook Incorporated
Samuel Engelman
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K180182
Trade/Device Name: Dual Lumen Ureteral Access Catheter, Flexi-Tip® Dual Lumen Ureteral Access Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EYB
Dated: August 13, 2018
Received: August 14, 2018

Dear Samuel Engelman:

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 and Part 809); 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
2018.09.14 10:17:38 -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

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)*
K180182

Device Name
Dual Lumen Ureteral Access Catheter
Flexi-tip® Dual Lumen Ureteral Access Catheter

Indications for Use *(Describe)*
This device is intended for injection of contrast medium and/or safety wire guide placement during percutaneous and transurethral access. The catheters that are 24 cm and 40 cm in length can be used in pediatric patients 12 years and over.

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

Dual Lumen Ureteral Access Catheter and
Flexi-Tip® Dual Lumen Ureteral Access Catheter
21 CFR §876.5130
Date Prepared: September 13, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Karthik Pillai, Ph.D.
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Primary Contact Phone:	(812) 339-2235 x104929
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Dual Lumen Ureteral Access Catheter and Flexi-Tip® Dual Lumen Ureteral Access Catheter
Common Name:	Catheter, Ureteral, Gastro-Urology
Classification Name:	Urological catheter and accessories
Regulation Number:	21 CFR §876.5130
Product Code:	EYB
Device Class:	Class II
Review Panel:	Gastroenterology/Urology

Predicate Device:

The predicate device is ACMI Corporation's Dual Lumen Catheter cleared under 510(k) Premarket Notification number K043581.

Device Description:

The Dual Lumen Ureteral Access Catheter is constructed from a dual-lumen, polyurethane tubing with ink marks and a tubing manifold with extension tubes. The catheter has a working length of 50 cm. The outer diameter of the catheter is 10.0 Fr and both lumens' inner diameter is 0.050 inches. The distal tip is notched to expose one lumen and create a 5.0 Fr tip with the other lumen. This device is manufactured both with and without a hydrophilic coating.

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The Flexi-Tip® Dual Lumen Ureteral Access Catheter is constructed from a dual-lumen, polyurethane tubing with ink marks and a tubing manifold with extension tubes. The catheter is available in lengths of 24, 40, and 50 cm. The outer diameter of the catheter is 10.0 Fr and both lumens' inner diameter is 0.050 inches. The distal tip is notched to expose one lumen and a flexible polyurethane tip is bonded to the tip of the other lumen. The Flexi-Tip® Dual Lumen Ureteral Access Catheter is available with hydrophilic coating and a radiopaque urethane tungsten marker. The Dual Lumen Ureteral Access Catheter and the Flex-Tip® Dual Lumen Ureteral Access catheters are sterilized by ethylene oxide and are packaged in peel-open pouches for single use.

Indications for Use:

This device is intended for injection of contrast medium and/or safety wire guide placement during percutaneous and transurethral access. The catheters that are 24 cm and 40 cm in length can be used in pediatric patients 12 years and over.

Comparison to Predicate Device:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Differences between the subject devices and the predicate device include a difference in indications for use, patient population, dimensions, and materials. Characteristics of the subject devices that differ from the predicate device are supported by testing and analysis.

	Predicate Device	**Subject Device**
	Dual Lumen Catheter	**Dual Lumen Ureteral Access Catheter and Flexi-Tip® Dual Lumen Ureteral Access Catheter**
510(k) Number	K043581	K180182
Manufacturer	ACMI Corporation (acquired by Olympus)	Cook Incorporated
Regulation Number	21 CFR §876.5130 Urological catheter and accessories.	Identical
Product Code	EYB	Identical
Classification Name	Urological catheter and accessories	Identical
Device Class	II	II
Indications for Use	The dual lumen ureteral catheter is designed for percutaneous and	This device is intended for injection of contrast medium and/or safety wire guide

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	Predicate Device	Subject Device
	Dual Lumen Catheter	**Dual Lumen Ureteral Access Catheter and Flexi-Tip® Dual Lumen Ureteral Access Catheter**
	transurethral access and is indicated as a conduit for multiple uses including, but not limited to, ureteral dilation, stone displacement, delivery of contrast material/anesthetic agents and guidewire placement.	placement during percutaneous and transurethral access. The catheters that are 24 cm and 40 cm in length can be used in pediatric patients 12 years and over.
Patient Population	Unknown	Adult, and Pediatric 12 years and over
Single- Use Only	Single- Use Only	Identical
Sterile	Yes	Yes
Sterilization Method	Not known	Ethylene Oxide
Flexible Tip	Yes	Available
Catheter Tip Diameter (Fr)	6.0	5.0, 6.0
Catheter Lumens	Two	Two
Lumen size (in)	.045	.050
Catheter Diameter (Fr)	10.0	10.0
Working Length (cm)	60	24, 40, 50
Radiopacity	Radiopaque Catheter	Radiopaque Catheter Shaft, Flexible Tip and Marker
Materials		
Hydrophilic Coating	Not known	Available (Surmodics)
Catheter Material	Radiopaque Polyethylene Tubing	Radiopaque Polyurethane Tubing

Performance Data:

The following testing was performed in order to demonstrate that the proposed Dual Lumen Ureteral Access Catheter and Flexi-Tip® Dual Lumen Ureteral Access Catheter met applicable design and performance requirements.

- Biocompatibility
- Sterilization
- Dimensional
- Lumen Patency

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- Blockage and Leakage
- Radiopacity
- Kinking
- Dynamic Friction Force
- Tensile
- Accelerated Age

Conclusion:

The results of these tests provide reasonable assurance that the Dual Lumen Ureteral Access Catheter and Flexi-Tip® Dual Lumen Ureteral Access Catheter will function as intended. The subject devices do not raise new questions of safety or effectiveness as compared to the predicate device.