June 17, 2019

Cook Incorporated
Chelsea Woods
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K182695
Trade/Device Name: Pigtail Ureteral Catheter Set
Pigtail Ureteral Catheter Sof-Flex® AQ®
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EYB
Dated: May 9, 2019
Received: May 10, 2019

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. 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/tray 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/tray. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for
Glenn B. Bell, Ph.D.
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*

K182695

Device Name
Pigtail Ureteral Catheter Set
Pigtail Ureteral Catheter Sof-Flex® AQ®

Indications for Use *(Describe)*

Indicated for drainage or irrigation in the urinary tract as well as 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.

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2.0 510(k) Summary

Pigtail Ureteral Catheter Set and Pigtail Ureteral Catheter Sof-Flex® AQ®
21 CFR §807.92
Date Prepared: May 8, 2019

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
Primary Contact Phone:	(812) 335-3575 x104007
Secondary Contact Phone:	(812) 335-3575 x104929
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Pigtail Ureteral Catheter Set Pigtail Ureteral Catheter Sof-Flex® AQ®
Device Common Name:	Catheter, Ureteral, Gastro-Urology
Regulation 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 the AQ® Hydrophilic Urological Catheter manufactured by Cook Urological, Inc, which was cleared under K962004.

Predicate Device:

- AQ® Hydrophilic Urological Catheter (K962004)

Reference Device:

- Open-End Ureteral Catheter Sof-Flex® (K171662)

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Device Description:

The Pigtail Ureteral Catheter Sets consist of a catheter and wire guide. The catheters are constructed from polyurethane tubing and have a proximal female Luer lock adapter constructed from polyamide. The catheters are available in 5, 6, and 7 French (Fr) and a length of 70 centimeters (cm). The distal end of the catheter has a single pigtail loop with six sideports. The catheter has ink marks denoting depth and body orientation. The stainless steel wire guides are coated with polytetrafluoroethylene (PTFE) and available in diameters of 0.038 and 0.045 inches (in) with a length of 145 cm.

The Pigtail Ureteral Catheter Sof-Flex® AQ® is a catheter with a hydrophilic coating. The catheters are constructed from polyurethane tubing and have a female Luer lock adapter constructed from polyamide. The catheters are available in 8.2 and 10 Fr and have a length of 56 cm. The distal end of the catheter has a single pigtail loop with 5 evenly spaced sideports around the pigtail loop. There are also 6 sideports spaced at 1 cm intervals just proximal to the pigtail loop on the same side of the catheter. For the next 10 cm after the sideports, on the straight portion of the catheter, there are no sideports. After which, there are 9 sideports placed at 1 cm intervals spiraled around the catheter across 8 cm.

The subject devices are provided sterile and are intended for one time use.

Indications for Use:

Indicated for drainage or irrigation in the urinary tract as well as access, advancement or exchange of wire guides.

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, length, and coating. Characteristics of the subject devices that differ from the predicate

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device are supported by testing and analysis. The substantial equivalence comparison of the subject devices to the predicate device is provided in the table below.

	Predicate Device	Subject Devices	
	AQ Hydrophilic Urological Catheter	**Pigtail Ureteral Catheter Set**	**Pigtail Ureteral Catheter Sof-Flex® AQ®**
510(k) Number	K962004	Subject of this Submission	Subject of this Submission
Manufacturer	Cook Urological, Inc (Merged with Cook Incorporated)	Cook Incorporated	
Regulation Number	876.5130 – Urological Catheter and accessories	Identical to Predicate	
Product Code	EYB – Catheter, Ureteral, Gastro-Urology	Identical to Predicate	
Device Class	II	Identical to Predicate	
Indications for Use	The AQ Hydrophilic Urological Catheters are intended for drainage, irrigation and/or retrograde pyelogram. The hydrophilic coating will allow the catheters to become lubricious which will reduce friction.	Indicated for drainage or irrigation in the urinary tract as well as access, advancement or exchange of wire guides.	
Catheter Diameter (Fr)	3 – 10	5, 6, 7	8.2, 10
Catheter Length (cm)	70	70	56
Catheter Material	Polyurethane, polyethylene, and vinyl	Polyurethane	
Distal End	Pigtail Coil, Straight, Flexi-Tip, Whistle Tip, Round Tip, Echotip®, Angled Tip, Spiral Tip, Cone Tip	Pigtail Coil	
Sideports	Sideports in coil and shaft	Identical to Predicate	
Ink Marks	Orientation Marker	Orientation Marker, Depth Marker	None
Coating	Hydrophilic	None	Hydrophilic
Radiopaque Catheter	Yes	Identical to Predicate	
Proximal Fitting	Luer Lock Connector	Identical to Predicate	
Wire Guide Compatibility (in)	0.025, 0.038, 0.045	0.038 and 0.045	0.038
Set Components	Catheter and Wire Guide, Catheter Only	Catheter and Wire Guide	Catheter Only
Packaging	Tyvek Pouch	Identical to Predicate	
Sterilization	EtO	Identical to Predicate	
SAL	10^{-6}	Identical to Predicate	

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Performance Data:

The following testing was performed in order to demonstrate that the subject devices, the Pigtail Ureteral Catheter Sets and Pigtail Ureteral Catheter Sof-Flex® AQ®, met applicable design and performance requirements.

- Biocompatibility
- Sterilization
- Radiopacity
- Visual Inspection
- Dimensional Evaluation
- Wire Guide Compatibility
- Leakage
- Flow Rate
- Kink Radius
- Curl Restoration
- Curl Retention Strength
- Tensile Strength
- Dynamic Friction

Conclusion:

The results of these tests support a conclusion that Pigtail Ureteral Catheter Sets and the Pigtail Ureteral Catheter Sof-Flex® AQ® will perform as intended. The subject devices do not raise new questions of safety or effectiveness as compared to the predicate device.