



February 1, 2018

Cook Incorporated  
Carly Powell  
Regulatory Affairs Specialist  
750 Daniels Way, P.O. Box 489  
Bloomington, IN 47402

Re: K171662

Trade/Device Name: Open-End Ureteral Catheter, Open-End Ureteral Catheter Sof-Flex, EchoTip  
Open-End Ureteral Catheter, Open-End Flexi-Tip Ureteral Catheter, Flexi-Tip  
Ureteral Catheter (Closed End), Whistle Tip Ureteral Catheter, Round Tip  
Ureteral Catheter, Spiral Tip Ureteral Access Catheter, Pediatric Ureteral  
Catheter

Regulation Number: 21 CFR§ 876.5130

Regulation Name: Urological Catheter and Accessories

Regulatory Class: II

Product Code: KOD

Dated: December 19, 2017

Received: December 20, 2017

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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**Benjamin R. Fisher -S**

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

## Indications for Use

510(k) Number (if known)  
K171662

### Device Name

Open-End Ureteral Catheter, Open-End Ureteral Catheter Sof-Flex, EchoTip Open-End Ureteral Catheter, Open-End Flexi-Tip Ureteral Catheter, Flexi-Tip Ureteral Catheter (Closed End), Whistle Tip Ureteral Catheter, Round Tip Ureteral Catheter, Spiral Tip Ureteral Access Catheter, Pediatric Ureteral Catheter

### Indications for Use (Describe)

Ureteral catheters are indicated for access and catheterization of the urinary tract, including the following applications:

- Delivery of contrast media
- Drainage of fluids from the urinary tract
- Delivery of irrigation fluids to the urinary tract
- Navigation of a tortuous ureter
- Access, advancement, or exchange of wire guides (open-ended catheters only)

The Pediatric Ureteral Catheter is indicated for access and catheterization of the urinary tract in pediatric patients, including the following applications:

- Delivery of contrast media
- Drainage of fluids from the urinary tract
- Delivery of irrigation fluids to the urinary tract
- Navigation of a tortuous ureter

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

### Ureteral Catheters As required by 21 CFR 807.92 Date Prepared: January 31, 2018

#### Submitted By:

Submission: Traditional 510(k) Premarket Notification  
Applicant: Cook Incorporated  
Contact: Carly Powell  
Applicant Address: Cook Incorporated  
750 Daniels Way  
Bloomington, IN 47404  
Contact Phone: (812) 339-2235 x104913  
Contact Fax: (812) 332-0281

#### Device Information:

Trade Name: Open-End Ureteral Catheter,  
Open-End Ureteral Catheter Sof-Flex,  
EchoTip Open-End Ureteral Catheter,  
Open-End Flexi-Tip Ureteral Catheter,  
Flexi-Tip Ureteral Catheter (Closed End),  
Whistle Tip Ureteral Catheter,  
Round Tip Ureteral Catheter,  
Spiral Tip Ureteral Access Catheter,  
Pediatric Ureteral Catheter

Common Name: Catheter, Urological  
Classification Name: Urological catheter and accessories  
Regulation, Class: 21 CFR §876.5130, Class II  
Product Code, Panel: KOD, Gastroenterology/Urology

#### Predicate Devices:

- Primary predicate device: Bard TigerTail Ureteral Catheter (K033719)
- Secondary predicate device: Porges Ureteral Catheters (K021856)

#### Device Description:

The Ureteral Catheter family is comprised of nine different types of Ureteral Catheters. The types of catheters include: Open-End Ureteral Catheter, Open-End Ureteral Catheter Sof-Flex, EchoTip Open-End Ureteral Catheter, Open-End Flexi-Tip Ureteral Catheter, Flexi-Tip Ureteral Catheter (Closed End), Whistle Tip Ureteral Catheter, Round Tip Ureteral Catheter, Spiral Tip Ureteral Access Catheter, and Pediatric Ureteral Catheter.

The Ureteral Catheters range in length from 10 to 125 cm. The catheters may be closed or open-ended. The Ureteral Catheters are sterile, single-use devices.

**Indications for Use:**

Ureteral catheters are indicated for access and catheterization of the urinary tract, including the following applications:

- Delivery of contrast media
- Drainage of fluids from the urinary tract
- Delivery of irrigation fluids to the urinary tract
- Navigation of a tortuous ureter
- Access, advancement, or exchange of wire guides (open-ended catheters only)

The Pediatric Ureteral Catheter is indicated for access and catheterization of the urinary tract in pediatric patients, including the following applications:

- Delivery of contrast media
- Drainage of fluids from the urinary tract
- Delivery of irrigation fluids to the urinary tract
- Navigation of a tortuous ureter

**Comparison to Predicate Devices:**

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate devices due to the similarities with their intended uses. Differences between the subject device and the predicate devices include dimensional variations and slight variations in materials. Characteristics of the subject device that differ from the predicate devices are supported by testing. These differences do not raise any new questions of safety and/or effectiveness. The substantial equivalence comparison of the subject device to the predicates is provided in the following table.

**Substantial Equivalence Comparison**

	<b>PRIMARY PREDICATE DEVICE</b>	<b>SECONDARY PREDICATE DEVICE</b>	<b>SUBJECT DEVICE</b>
	<b>Bard - TigerTail Ureteral Catheter</b>	<b>Porges Ureteral Catheters</b>	<b>Ureteral Catheters</b>
<b>510(k) Number</b>	K033719	K021856	Subject of Submission
<b>Manufacturer</b>	C.R. Bard Inc.	Porges S.A.	Cook Incorporated
<b>Regulation</b>	21 CFR §876.5130	21 CFR §876.5130	Identical
<b>Product Code</b>	KOD	EYB	Identical to primary predicate
<b>Classification Name</b>	Catheter, Urological	Catheter, Ureteral, Gastro-Urology	Identical to primary predicate
<b>Classification</b>	II	Identical	Identical
<b>Indications for Use</b>	The Bard TigerTail Ureteral Catheter is intended to facilitate drainage and retrograde pyelogram of the	Ureteral catheterization: -Drainage catheters -Catheters for retrograde ureteropyelography	Ureteral catheters are indicated for access and catheterization of the urinary tract, including the following applications:

	<b>PRIMARY PREDICATE DEVICE</b>	<b>SECONDARY PREDICATE DEVICE</b>	<b>SUBJECT DEVICE</b>
	<b>Bard - TigerTail Ureteral Catheter</b>	<b>Porges Ureteral Catheters</b>	<b>Ureteral Catheters</b>
	upper urinary tract. This catheter will allow access to and navigation of a tortuous ureter using standard endoscopic techniques.	-Interventional catheters	<ul style="list-style-type: none"> <li>• Delivery of contrast media</li> <li>• Drainage of fluids from the urinary tract</li> <li>• Delivery of irrigation fluids to the urinary tract</li> <li>• Navigation of a tortuous ureter</li> <li>• Access, advancement, or exchange of wire guides (open-ended catheters only)</li> </ul> <p>The Pediatric Ureteral Catheter is indicated for access and catheterization of the urinary tract in pediatric patients, including the following applications:</p> <ul style="list-style-type: none"> <li>• Delivery of contrast media</li> <li>• Drainage of fluids from the urinary tract</li> <li>• Delivery of irrigation fluids to the urinary tract</li> <li>• Navigation of a tortuous ureter</li> </ul>
<b>Catheter OD (Fr size)</b>	4-6 Fr	3-12 Fr	3-9 Fr
<b>Catheter Length (cm)</b>	70 cm	Unknown	10, 15, 70, 85, 120
<b>Materials</b>			
<b>Catheter Material</b>	Radiopaque Polyurethane	Radiopaque polymer-polyvinyl chloride and polyamide mixture	Radiopaque Polyvinyl chloride or Polyurethane Radiopaque tubing or Polytetrafluoroethylene
<b>Components</b>	The following components may be included: Adapter Stylet/Wire	Unknown	Identical to primary predicate

**Reference Devices:**

In addition to the predicate devices, the following reference devices are used to help make a determination of substantial equivalence:

- The Rutner Universal Wedge Catheter (Cook Inc., K760858)
- The C-Flex Ureteral Stent Set (Cook Inc., K162104)

**Performance Data:**

The subject devices underwent the applicable testing listed below to ensure reliable design and performance under the testing parameters. Performance and biocompatibility

testing were conducted in accordance with the following applicable FDA guidance documents to confirm the reliable performance of critical device characteristics.

Performance – Testing shows that the subject device conforms to the performance testing requirements based on intended use. All predetermined acceptance criteria were met.

Test Performed	Guidance Document
Tensile Strength – Testing shows that there should be no fracture of catheter tips or shafts during proper clinical use.	N/A
Leakage and Lumen Blockage – Testing evaluated lumen blockage and leakage in a pressurized flow test. Lumen patency, dimensional length, inner diameter, and outer diameter were determined.	
Radiopacity – Testing shows that the mean radiopacity met the acceptance criteria and evaluated radiopacity by subjecting the ureteral catheters to a comparative fluoroscopic evaluation.	
Kink Radius – Testing determined the kink radius of the ureteral catheter tubing.	
Catheter-Hub Bond – Testing determined the tensile strength of the hub-to-shaft bond.	

Biocompatibility – Testing shows that the subject device conforms to the biocompatibility requirements based on its intended use. All predetermined acceptance criteria were met.

Testing Performed	Guidance Document
Cytotoxicity – ISO MEM Elution	Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
Sensitization – Guinea Pig Maximization	
Irritation/Intracutaneous Reactivity – Intracutaneous Study	

All predetermined acceptance criteria were met.

**Conclusion:**

The data included in this submission indicate that the subject devices do not raise new questions of safety or effectiveness compared to the predicate device. This supports a determination of substantial equivalence.