April 19, 2018

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

Re: K172588
Trade/Device Name: Balloon Ureteral Dilator and Balloon Ureteral Dilator Set
Regulation Number: 21 CFR§ 876.5470
Regulation Name: Ureteral Dilator
Regulatory Class: II
Product Code: EZN
Dated: March 8, 2018
Received: March 9, 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. 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); 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) 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See *PRA Statement below.*

Indications for Use

510(k) Number *(if known)*
K172588

Device Name
Balloon Ureteral Dilator and Balloon Ureteral Dilator Set

Indications for Use *(Describe)*

The Balloon Ureteral Dilator and Balloon Ureteral Dilator Set is intended for ureteral dilation prior to ureteral stone manipulation or ureteroscopy and dilation of the intramural 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

Balloon Ureteral Dilator and Balloon Ureteral Dilator Set
21 CFR §807.92
Date Prepared: April 19, 2018

Submitted By:

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

Device Information:

Trade Name:	Balloon Ureteral Dilator and Balloon Ureteral Dilator Set
Common Name:	Ureteral Dilator
Regulation Number:	21 CFR §876.5470
Regulation Name:	Ureteral Dilator
Regulatory Class:	Class II
Product Code:	EZN
Classification Panel:	Gastroenterology/Urology

Predicate Device:

- The Balloon Ureteral Dilator and Balloon Ureteral Dilator Set is substantially equivalent to the following device: Ascend™ Balloon Dilation Catheter (K970041, Cook Urological, Inc.) cleared on March 19, 1997.

Device Description:

The Balloon Ureteral Dilator Set includes the balloon ureteral dilator, a wire guide, a 10 mL syringe, an endoscopic cap and a pin-vise handle. Balloon ureteral dilators can be purchased separately.

The balloon ureteral dilator is composed of a radiopaque dilator fitted with a polyethylene balloon. The balloon ureteral dilator is available in 5.0 or 7.0 French and is 65 centimeters in length. The balloon is located on the distal end of the dilator and has diameters of 5 or 6 millimeters with lengths of 4 or 10 centimeters when inflated. The balloon has a maximum inflation pressure of 40 or 60 psi, depending on the diameter and length of the balloon. Additionally, radiopaque marker bands are placed at the proximal and distal ends of the balloon to provide fluoroscopic visibility.
Additional set components in the Balloon Ureteral Dilator Set include a straight safety wire guide, endoscopic cap, pin-vise handle, and syringe. The wire guide has a diameter of 0.028 or 0.038 inches and a length of 145 centimeters. The endoscopic cap and a pin-vise handle are provided to stabilize the wire guide during introduction. The syringe is a 10 mL luer-lock syringe provided for balloon inflation.

The Balloon Ureteral Dilator and Balloon Ureteral Dilator Set is provided sterile for one-time use.

Intended Use:
The Balloon Ureteral Dilator and Balloon Ureteral Dilator Set is intended for ureteral dilation prior to ureteral stone manipulation or ureteroscopy and dilation of the intramural ureter.

Comparison to Predicate:
The Balloon Ureteral Dilator and Balloon Ureteral Dilator Set and the predicate device, the Ascend™ Balloon Dilation Catheter (K970041), are substantially equivalent in that these devices are identical 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 balloon characteristics. The differences between the dimensions and balloon characteristics of the subject and predicate devices are dimensions, material, and balloon characteristics. 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.

Balloon Ureteral Dilator and Balloon Ureteral Dilator Set Substantial Equivalence Comparison

	PREDICATE DEVICE	SUBJECT DEVICE
	Ascend™ Balloon Dilation Catheter	**Balloon Ureteral Dilator and Balloon Ureteral Dilator Set**
Manufacturer	Cook Incorporated (formerly Cook Urological, Inc.)	Cook Incorporated
510(k)	K970041	Subject of this submission
Regulation	21 CFR §876.5470	Identical to the predicate device
Product Code	EZN	Identical to the predicate device
Classification	II	Identical to the predicate device
Indications for Use	Used for ureteral dilation prior to ureteral stone manipulation or ureteroscopy, and dilation of the intramural ureter.	Identical to the predicate device
Catheter/Dilator O.D. (Fr)	7.0	5.0, 7.0
Catheter/Dilator Length (cm)	40-65	65
Catheter/Dilator Material	Polyurethane	Radiopaque Polyethylene, clear polyethylene
Inflated Balloon O.D. (mm)	5.0, 6.0, 7.0, 8.0, 10.0	5.0, 6.0
Inflated Balloon Length (cm)	4.0, 6.0, 10.0, 12.0	4.0, 10.0
Balloon Material	Polyethylene terephthalate (PET)	Polyethylene
Maximum Balloon Inflation Pressure	14, 16, 17, 19, 22 atm	40 psi, 60 psi (2.72 atm, 4.08 atm)
Wire Guide O.D. (inch)	0.038	0.028, 0.038
Wire Guide Length (cm)	145	Identical to the predicate device
Wire Guide Material	Stainless Steel	Identical to the predicate device
Markerbands	Not applicable	5 Fr - Stainless Steel 7 Fr - Tungsten
Sterilization Method	Ethylene Oxide	Identical to the predicate device

Performance Data:

The subject device, Balloon Ureteral Dilator and Balloon Ureteral Dilator Set, 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:

1. Radiopacity
2. Pressure Resistance for Dilatation Balloons
3. Kink Radius Testing
4. Balloon Rated Burst Pressure (RBP)
5. Dimensional Verification of Balloon upon inflation

6. Balloon Deflation Testing
7. Tensile Testing
8. Dimensional Verification
9. Biocompatibility
    - Cytotoxicity, Sensitization, and Irritation/Intracutaneous

Conclusion:

The results of performance testing confirm that the Balloon Ureteral Dilator and Balloon Ureteral Dilator Set meets the design input requirements based on the intended use and support the conclusion that this device does not raise new questions of safety or effectiveness and is substantially equivalent to the predicate device, the Ascend™ Balloon Dilation Catheter (Cook Urological, Inc., K970041).