July 17, 2018

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

Re: K173654
Trade/Device Name: Ureteral Dilator Sets
Ureteral Dilators
Regulation Number: 21 CFR§ 876.5470
Regulation Name: Ureteral Dilator
Regulatory Class: II
Product Code: EZN
Dated: June 27, 2018
Received: June 28, 2018

Dear Kotei Aoki:

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,

Glenn B. Bell -S

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)*
K173654

Device Name
Ureteral Dilator Sets
Ureteral Dilators

Indications for Use *(Describe)*
The Ureteral Dilator Sets are intended for the dilation of the ureter prior to ureteroscopy or stone manipulation.

The Ureteral Dilators are intended for the dilation of the ureter prior to ureteroscopy or stone manipulation.

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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K173654
Ureteral Dilator Sets
Ureteral Dilators
21 CFR §807.92
Date Prepared: 27 June 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Kotei Aoki
Email:	regsubmissions@cookmedical.com
Contact Phone Number:	(812) 335-3575 x102630
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Ureteral Dilator Sets** **Ureteral Dilators**
Common Name:	Dilator, Catheter, Ureteral
Classification Name:	Ureteral Dilator
Regulation:	21 CFR §876.5470
Product Code:	EZN
Device Class:	II
Classification Panel:	Gastroenterology/Urology

Predicate Device:

The Ureteral Dilator Sets, and each individual Ureteral Dilator, is substantially equivalent to the following device: the AQ Hydrophilic Dilator (K961904, Cook Urological Inc.) cleared on October 18, 1996.

Device Description:

The Ureteral Dilator Sets, and each individual Ureteral Dilator, are used for dilation of the ureter prior to ureteroscopy and/or stone manipulation. The Ureteral Dilator Sets are available in one of three sets: a set of 6 dilators, a set of 7 dilators and a wire guide, or a set of 9 dilators and a wire guide. The dilators are manufactured from either radiopaque ethylene vinyl acetate (EVA) or fluorinated ethylene propylene (FEP). Dilators manufactured with EVA are also available with hydrophilic coating. Dilators are also

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available individually. The wire guide is a stainless steel fixed core wire guide. The Ureteral Dilators and the Ureteral Dilator Sets are sterilized by ethylene oxide and intended for one-time use.

All Ureteral Dilators are manufactured with a length of 60 centimeters and range from 6.0 French to 18.0 French in diameter. The distal end of the dilators is tapered to a 0.040-inch diameter endhole with the taper measuring 0.8-2.5 centimeters from the distal end, depending on the device French size. Additionally, the French size of each dilator is stamped at the proximal end.

The stainless steel fixed cored wire guide is manufactured with a diameter of 0.038 inches (0.97 millimeters) and a length of 145 centimeters.

Indications for Use:

The Ureteral Dilator Sets are intended for the dilation of the ureter prior to ureteroscopy or stone manipulation.

The Ureteral Dilators are intended for the dilation of the ureter prior to ureteroscopy or stone manipulation.

Comparison to Predicate Device:

The Ureteral Dilator Sets, and each individual Ureteral Dilator, and the predicate device, the AQ Hydrophilic Dilator (K961904), are substantially equivalent in that these devices have the similar intended use and are identical in technological characteristics and method of placement. Additionally, the proposed devices have similar indications for use and dimensions as the predicate device. The differences between the proposed device and the predicate device, including the materials, dimensions, and indications for use do not raise any new issues of safety and effectiveness.

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Table 1: Substantial Equivalence Table

	PREDICATE DEVICE	SUBJECT DEVICE
	AQ Hydrophilic Dilators (K961904)	**Ureteral Dilator Sets**
Regulation	21 CFR §876.5520 21 CFR §876.5470	21 CFR §876.5470
Product Code	KOE, EZN	EZN
Classification	II	Identical
Indications for Use	Intended to dilate the suprapubic and/or nephrostomy fascial tract, urethra, and ureters	Intended for dilation of the ureter prior to ureteroscopy or stone manipulation
Device for One-Time Use	Yes	Identical
Distal Taper	Yes	Identical
Endhole Diameter	0.040 in	Identical
Set Components	Dilator, Wire Guide	Identical
Sterilization Method	EtO	Identical
Sterility Assurance Level	10^{-6}	Identical
Dilator O.D.	5.0 – 36.0 Fr.	6.0 – 18.0 Fr.
Dilator Length	20 – 60 cm	60 cm
Dilator Material	Polyurethane, Polyethylene, Vinyl	Ethylene Vinyl Acetate Fluorinated Ethylene Propylene
Hydrophilic Coating	Yes	Optional (EVA only)
Packaging	Tyvek-Poly Pouch	Tray (sets only) Tyvek-Poly Pouch Tyvek Peel Pouch

Technological Characteristics:

The subject devices, Ureteral Dilator Sets and Ureteral Dilators, were subjected to the following applicable testing to assure reliable design and performance under the specified testing parameters:

Bench Testing (including time zero and applicable three-year accelerated aged testing)

- Tensile Testing – The peak load preceding failure shall be greater than or equal to 15 N. Testing performed on the dilator shaft per applicable ISO standards demonstrated that the devices met the acceptance criteria.
- Kink Resistance Testing – The dilator shaft shall resist kinking at 80° angle. The dilator tip shall fit over a 0.038 inch guide wire.
- Dilator Tip Rollback Testing – The tip of the dilator shall be successfully introduced through the urethane membrane without showing any signs of damage such as rollback, buckle or kink at the tip. Testing performed per applicable ISO standards demonstrated that the dilator will not kink, buckle or rollback.

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- Lubricity Testing – The peak load during lubricity testing of the hydrophilic coated region of the dilators shall be less than the peak load during lubricity testing of the uncoated dilators.
- Dimensional Verification – The length of the dilators shall be 60 cm ± 1 cm. FEP dilators shall include a handle at the proximal end to facilitate removal of the dilator. Dilator markings shall be legible, defined as being able to read markings on dilators. Testing performed demonstrated that the test specimens' dimensions are within the specified tolerances. Testing performed demonstrated that the dilator is compatible with the wire guide.
- Radiopacity –Dilators shall be radiopaque in compliance with the methods detailed in ASTM F640-12. Testing performed demonstrated that the devices are visible in the radiographic image.

Biocompatibility Testing:

- Per ISO 10993-1 and FDA guidance, testing for cytotoxicity, sensitization, and intracutaneous irritation demonstrated the biocompatibility of the subject device.

Sterility Testing:

- The established method used to validate the sterilization cycle is consistent with the half-cycle method as described in ISO 11135:2014.
- Residual levels of ethylene oxide (EO) and ethylene chlorohydrin (ECH) have been evaluated and verified to be no greater than the maximum limits as specified in ANSI/AAMI/ISO 10993-7:2008(R)2012.
- The subject device is not an implant, nor labeled non-pyrogenic, nor intended to be in contact with intravascular, intralymphatic, or intrathecal fluid systems. Therefore, these devices do not require testing for the presence of bacterial endotoxins according to USP<161>.

Packaging Integrity and Distribution Testing:

- Packaging integrity testing after simulated distribution of these packaging materials has been performed on a worst-case representative device. Simulated distribution testing was performed according to ASTM D4169-16. All test methods are as recommended in Annex B of AAMI/ISO 11607-1:2006/(R)2015.

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Conclusion:

The results of these tests confirm that the Ureteral Dilator Sets, and each individual Ureteral Dilator, meet 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, AQ Hydrophilic Dilator (Cook Urological, Inc., K961904).