July 30, 2018

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

Re: K181431
Trade/Device Name: Laser Ureteral Catheter
Regulation Number: 21 CFR§ 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 31, 2018
Received: June 1, 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. 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)*
K181431

Device Name
Laser Ureteral Catheter

Indications for Use *(Describe)*
The Laser Ureteral Catheter is intended for protection and delivery of a laser fiber in the urinary tract.

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

Laser Ureteral Catheter
21 CFR 878.4810
Date Prepared: July 30, 2017

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 x104913
Contact Fax Number:	(812) 332-0281

Device Information:

Trade Name:	**Laser Ureteral Catheter**
Common Name:	Powered Laser Surgical Instrument
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Regulation:	21 CFR 878.4810, Product Code GEX
Device Class/Classification Panel:	Class II, General & Plastic Surgery

Predicate Device:

The Laser Ureteral Catheter is substantially equivalent to the following device:

- K960768 Laser Fiber Delivery/Cleaning Catheter (Cook Urological Inc.). The Laser Fiber Delivery/Cleaning Catheter is used to protect the delivery of a laser ablation fiber for periodic, intraoperative cleaning of charred, thermally degraded tissue from the laser fiber and for irrigation of the surgical site.

Reference Device:

- K171662 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

Device Description:

The Laser Ureteral Catheter is a single lumen catheter available in a diameter of 7.1 French and a length of 40 centimeters. The Laser Ureteral Catheter is manufactured from polyethylene tubing, with a proximal female Luer lock adapter and connector cap, and male Luer lock adapter and connector cap with a cap seal. The device is provided sterile and intended for one-time use.

Indications for Use:

The Laser Ureteral Catheter is intended for protection and delivery of a laser fiber in the urinary tract.

Comparison to Predicate:

The Laser Ureteral Catheter and the predicate device, Laser Fiber Delivery/Cleaning Catheter (K960768), are substantially equivalent in indications for use; these devices have similar design, technological characteristics, construction and function. Both are catheters intended to protect the delivery of a laser fiber. The Laser Ureteral Catheter and the reference device Ureteral Catheter (K171662) are similar in dimension, material, and these devices are both used in the ureter.

The intended uses for the Laser Fiber Delivery/Cleaning Catheter (K960768), and the subject device Laser Ureteral Catheter are fundamentally identical; "intended to be used to protect and deliver a laser fiber". The predicate has a broader indication for general surgery, whereas the subject device is specifically indicated for the urinary tract. The addition of this specific indication for the use in urinary tract does not raise any new questions of safety and effectiveness, since predicate is indicated for general surgery. Additionally, the access and catheterization of the urinary tract using a ureteral catheter is supported by the reference device Ureteral Catheter (K171662). The subject device and the reference device, Ureteral Catheters (K171662), are both indicated to access and catheterize the urinary tract.

The subject and predicate device have similar intended uses, and therefore, no new questions of safety or effectiveness are raised. A comparison of the intended uses and technological characteristics of the subject, reference and predicate devices is provided in Table 2.0-1.

Table 2.0-1 Comparison Table

	PREDICATE DEVICE	REFERENCE DEVICE	SUBJECT DEVICE
	Laser Fiber Delivery/Cleaning Catheter	**Ureteral Catheters**	**Laser Ureteral Catheter**
Manufacturer	**Cook Urological, Inc**	**Cook Incorporated**	**Cook Incorporated**
510(k)	K960768	K171662	Subject of this submission
Regulation	21 CFR §878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.	21 CFR §876.5130 Catheter, Ureteral, General & Plastic Surgery	21 CFR §878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.
Product Code	GEX	KOD	GEX
Classification	II	II	Identical
Indications for Use	The Laser Fiber Delivery/Cleaning Catheter is intended to be used to protect the delivery of a laser ablation fiber for periodic, intraoperative cleaning of charred, thermally degraded tissue from the laser fiber and for irrigation of the surgical site. The 5.7 Fr Laser Fiber Delivery/Cleaning Catheter will accept laser fibers up to 1250 microns (0.050 inch). The 8.0 Fr Laser Fiber Delivery/Cleaning Catheter will accept fibers up to 1500 microns (0.060 inch).	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	The Laser Ureteral Catheter is intended for protection and delivery of a laser fiber in the urinary tract.

Table 2.0-1 Comparison Table (continued)

	PREDICATE DEVICE	REFERENCE DEVICE	SUBJECT DEVICE
	Laser Fiber Delivery/Cleaning Catheter	**Ureteral Catheters**	**Laser Ureteral Catheter**
Catheter Diameter (Fr)	5.7-accept fibers up to 1250 microns (0.05 inch), 8.0-accept fibers up to 1500 microns (0.06 inch)	3-9	7.1
Catheter Length (cm)	25-40	10, 15, 70, 85, 120	40
Catheter Material	Polyethylene	Radiopaque Polyvinyl chloride or Polyurethane Radiopaque tubing or Polytetrafluoroethylene	Polyethylene Radiopaque Tubing
Maximum shelf-life (years)	Unknown	3	3
Sterilization Method	EtO	EtO	Identical
Packaging	Tyvek-Poly pouch	Tyvek polyethylene peel-open pouch	Tyvek-PET/ LDPE

Performance Data:

The subject device 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
Compatibility and Dimensional Testing – Testing ensures dimensional and compatibility requirements were met.	N/A
Tensile Strength – Testing shows that there should be no fracture of catheter shaft and hub-to-shaft.	
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.	

- 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 device does not raise new questions of safety or effectiveness compared to the predicate device, Laser Fiber Delivery/Cleaning Catheter (K960768), which supports a determination of substantial equivalence.