March 7, 2018

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

Re: K171810
Trade/Device Name: Cone Tip Ureteral Catheter, Rutner Universal Wedge Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: KOD
Dated: January 31, 2018
Received: February 1, 2018

Dear Yan Li:

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) 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171810

Device Name
Cone Tip Ureteral Catheter

Indications for Use *(Describe)*
The Cone Tip Ureteral Catheter is intended for retrograde pyelogram.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K171810

Device Name
Rutner Universal Wedge Catheter

Indications for Use *(Describe)*
The Rutner Universal Wedge Catheter is intended for retrograde pyelogram. The 4.0 Fr Rutner Universal Wedge Catheter is indicated for pediatric population 2 years and older.

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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COOK INCORPORATED
750 DANIELS WAY
BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

2.0 510(k) SUMMARY

Cone Tip Ureteral Catheter
Rutner Universal Wedge Catheter
21 CFR §807.92
Date Prepared: March 5, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Yan Li
	Karthik Pillai
Applicant Address:	Cook Incorporated
	750 Daniels Way
	Bloomington, IN 47404
Contact Phone Number:	(812)335-3575x104987
Contact Fax Number:	(812)332-0281

Device Information:

Trade Names:	Cone Tip Ureteral Catheter
	Rutner Universal Wedge Catheter
Common Name:	Urological Catheter
Classification Name:	Urological catheter and accessories
Device Class/Review Panel:	Class II, Gastroenterology/Urology
Regulation:	21 CFR §876.5130
Product Code:	KOD

Predicate Devices:

Cone Tip Ureteral Catheter

- Rutner Universal Wedge Catheter - Cook Incorporated, K760858
- Van-Tec Open Ended Cone Tip Ureteral Catheter (Boston Scientific Cone Tip Ureteral Catheter), K870694*

Rutner Universal Wedge Catheter

- Rutner Universal Wedge Catheter - Cook Incorporated, K760858

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BLOOMINGTON, IN 47404 USA
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

- Van-Tec Open Ended Cone Tip Ureteral Catheter (Boston Scientific Cone Tip Ureteral Catheter), K870694*

  ***** *Note: Boston Scientific is the current owner of K870694 Van-Tec Open Ended Cone Tip Ureteral Catheter.*

Device Description:

- **Cone Tip Ureteral Catheter**

The Cone Tip Ureteral Catheter is used for retrograde pyelogram. The product consists of a straight, tipped catheter. The distal tip is in a cone formation and intended to temporarily occlude the ureteral orifice. The catheter tip and tubing shaft are made of radiopaque polyvinyl chloride material. The catheter is available in outer diameters of 4.8 and 6.0 French with corresponding tip diameters of 8.0 and 10.0 French respectively. The total working length of the device measures 70 centimeters. All French sizes are available with a closed distal end, except the 4.8 French catheters which are also available with an open end. Catheters with closed distal ends include one side port near the tip, whereas catheters with open distal ends do not include a side port. The radiopaque vinyl tubing shaft has an adapter on the proximal end and incremental graduation marks placed along the distal 50 centimeters of the catheter surface.

- **Rutner Universal Wedge Catheter**

The Rutner Universal Wedge Catheter is used for retrograde pyelogram. The distal tip is made of polyvinyl chloride radiopaque material and its configuration is designed to occlude the ureteral orifice and stabilize the catheter by temporarily wedging the orifice. The catheter tubing shaft is manufactured from non-radiopaque nylon with an adapter located at the proximal end. The catheter is available in outer diameters of 4.0 or 5.0 French and a total device length of 70 centimeters. The outer diameter of the tip is available in 8.0 and 14.0 French. Based upon the device size, the distal tip may occlude an opening of 3.0 to 8.0 French or 4.0 to 14.0 French, respectively. A single sideport is located in the distal end of the catheter.

Indications for Use:

- The Cone Tip Ureteral Catheter is intended for retrograde pyelogram.
- The Rutner Universal Wedge Catheter is intended for retrograde pyelogram. The 4.0 Fr Rutner Universal Wedge Catheter is indicated for pediatric population 2 years and older.

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Comparison to Predicates:

The Cone Tip Ureteral Catheter and the predicate devices, the Rutner Universal Wedge Catheter (K760858) and Van-Tec Open Ended Cone Tip Ureteral Catheter (K870694) are substantially equivalent in that these devices share similar indications for use, materials, dimensions, designs, and technological characteristics.

The Rutner Universal Wedge Catheter and the predicate devices, the Rutner Universal Wedge Catheter (K760858) and Van-Tec Open Ended Cone Tip Ureteral Catheter (K870694), are substantially equivalent in that these devices share similar indications for use, materials, dimensions, designs, and technological characteristics.

While many characteristics are similar, there are minor differences between the subject devices and the predicate devices. These differences include updates to the indications for use, materials, and dimensions of the subject devices. The device modifications are supported by testing and do not raise new issues of safety or effectiveness of the subject device.

Performance Data:

The Cone Tip Ureteral Catheter and the Rutner Universal Wedge Catheter were 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. Biocompatibility
2. Dimensional Verification
3. Blockage And Leakage Testing
4. Kink Radius Testing
5. Tensile Testing
6. Shelf Life (3 Years Accelerated Age)

Conclusion:

The results of testing support a conclusion that the Cone Tip Ureteral Catheter and the Rutner Universal Wedge Catheter meet the design input requirements based on their intended uses. The testing also demonstrates that the minor differences in the subject devices do not raise new issues of safety or effectiveness and therefore support a determination of substantially equivalence to the predicate devices, the Rutner Universal Wedge Catheter (K760858) and Van-Tec Open Ended Cone Tip Ureteral Catheter (K870694).