August 5, 2019

COOK Incorporated
Johnathan Liu
Regulatory Affairs Manager
750 Daniels Way
Bloomington, IN 47404

Re: K183323
Trade/Device Name: UPJ Occlusion Balloon Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EYB
Dated: July 19, 2019
Received: July 22, 2019

Dear Johnathan Liu:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, Ph.D.
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K183323

Device Name
UPJ Occlusion Balloon Catheter

Indications for Use *(Describe)*
Used to temporarily occlude the ureteropelvic junction to prevent stone fragments from entering the ureter during percutaneous lithotripsy, and for injection of contrast medium.

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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2.0 510(k) Summary

UPJ Occlusion Balloon Catheter
21 CFR §807.92
Date Prepared: August 5, 2019

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Primary Contact:	Johnathan Liu
Secondary Contact:	Karthik Pillai, PhD
Email:	RegSubmissions@cookmedical.com
Contact Phone:	(812)-335-3575 x104509
Contact Fax:	(812)-332-0281

Device Information:

Trade Name:	**UPJ Occlusion Balloon Catheter**
Device Common Name:	Catheter, Ureteral, Gastro-Urology
Classification Name:	Urological Catheter and Accessories
Classification Regulation:	21 CFR §876.5130
Product Code:	EYB
Device Classification:	Class II
Review Panel:	Gastroenterology/Urology

Predicate Device:

Occluder™ Occlusion Balloon Catheter (K133750)

Device Description:

The UPJ Occlusion Balloon Catheter is composed of a balloon catheter, a removable inflation/injection adapter, a 1 mL syringe, and a wire guide assembly. The UPJ Occlusion Balloon Catheter is manufactured from a double lumen polyurethane radiopaque tubing with a working length of 75 centimeters. The smaller lumen is designed for balloon inflation, while the larger lumen fits over the wire guide assembly. The distal balloon is manufactured from silicone

and has an approximate inflation volume of 4 mL. The inflation/injector adapter is removable, allowing for a cystoscope to be removed after the catheter is in place. The wire guide assembly is manufactured in 0.028- or 0.038-inch diameter stainless steel coils. The stainless-steel coils are coated with polytetrafluoroethylene and measure 80 centimeters. The wire guide assembly is designed to be placed through the small lumen of the balloon catheter.

The UPJ Occlusion Balloon Catheter is supplied sterile, intended for one-time use only, and packaged in a peel-open pouch with a shelf-life of 3 years.

Indications for Use:

Used to temporarily occlude the ureteropelvic junction to prevent stone fragments from entering the ureter during percutaneous lithotripsy, and for injection of contrast medium.

Comparison to Predicate Device:

The subject device, UPJ Occlusion Balloon Catheter, and the predicate device, Occluder™ Occlusion Balloon Catheter (K133750), are similar in intended uses, fundamental technological characteristics, and methods of operation. Differences between the characteristics of the subject device and the predicate device include:

- Indications for Use
- Design Features
- Dimensions
- Materials

Differences between the characteristics of the subject device and the predicate device are supported by testing. The subject device raises no new questions of safety and effectiveness as compared to the predicate device.

Performance Data:

The following testing was performed to demonstrate that the UPJ Occlusion Balloon Catheter met applicable design requirements.

- Biocompatibility
- Tensile Strength
- Kink Radius
- Leakage and Lumen Blockage
- Radiopacity
- Balloon Fatigue and Burst
- Dimensional Measurement and Compatibility

Results of the testing provide reasonable assurance that the subject device, UPJ Occlusion Balloon Catheter will perform as intended. The subject device does not raise new questions of safety or effectiveness as compared to the predicate devices. In conclusion, the results of these tests support a determination of substantial equivalence to the predicate device.