May 2, 2018

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

Re: K180028
Trade/Device Name: Cook 810 Set, Desilets-Hoffman Introducer Set
Regulation Number: 21 CFR§ 876.5470
Regulation Name: Ureteral Dilator
Regulatory Class: II
Product Code: EZN
Dated: March 27, 2018
Received: March 28, 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 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)*
K180028

Device Name
Cook 810 Set, Desilets-Hoffman Introducer Set

Indications for Use *(Describe)*
The Cook 810 Set is used for retrograde or antegrade ureteral access and to facilitate wire guide exchange.

The Desilets-Hoffman Introducer Set is used for retrograde or antegrade ureteral access and to facilitate wire guide exchange.

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

Ureteral Introducer Sets
As required by 21 CFR 807.92
Date Prepared: May 1, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Carly Powell Andrew Breidenbach
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 335-3575 x104913
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Cook 810 Set, Desilets-Hoffman Introducer Set
Common Name:	Ureteral dilator
Classification Name:	Ureteral dilator
Regulation, Class:	21 CFR §876.5470, Class II
Product Code, Panel:	EZN, Gastroenterology/Urology

Predicate Device:

- Boston Scientific's 8/10 Dilator/Sheath Set, cleared for commercial distribution under 510(k) number K851144

Device Description:

The Ureteral Introducer Sets is a bundle of two Ureteral Introducer Sets, composed of the Cook® 810 Set and Desilets-Hoffman Introducer Set. The Cook 810 Set is composed of a dilator and a delivery sheath, which is used for retrograde or antegrade ureteral access and to facilitate wire guide exchange. To use this device, antegrade (i.e., through a percutaneous tract) or retrograde (i.e., transurethral) access is achieved using a wire guide up to 0.038 inches in outer diameter, using standard access techniques. Next, the dilator is inserted over the wire guide and used to dilate the ureter/ureteral orifice. The physician would then place the delivery sheath over the dilator to dilate the anatomy to 10 French before placing the tip of the sheath into the desired anatomical location. The dilator is withdrawn while maintaining the position of the introducer sheath. Wires may then be placed/exchanged through the sheath, and the delivery sheath is subsequently removed from the patient. The dilator is an outer diameter of 8 French and 88

centimeters (cm) in length. Both ends of the dilator have smooth round tips and both tips are tapered at 5 millimeters (mm) as well. The sheath is an outer diameter of 8.5 French and 30 or 50 cm in length, depending on the selected set.

The Desilets-Hoffman Introducer Set is used for retrograde or antegrade ureteral access and to facilitate wire guide exchange. The Desilets-Hoffman Introducer Set includes a delivery sheath and dilator. The delivery sheath is 10 French and 30 cm in length. The dilator is 8 French and available in 70 or 88 cm in length. One of the sets ("RB" version) has a radiopaque band on the delivery sheath to aid in fluoroscopic visualization during placement.

Indications for Use:
Ureteral Introducer Sets are indicated as follows:

- The Cook 810 Set is used for retrograde or antegrade ureteral access and to facilitate wire guide exchange.
- The Desilets-Hoffman Introducer Set is used for retrograde or antegrade ureteral access and to facilitate wire guide exchange.

Comparison to Predicate Device:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Differences between the subject devices and the predicate device include slight dimensional variations and variations in materials. Characteristics of the subject devices that differ from the predicate device are supported by testing. These differences do not raise any new questions of safety and/or effectiveness.

Performance Data:

The subject devices 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 applicable performance standards and FDA guidance documents to confirm the reliable performance of critical device characteristics.

- Dimensional Testing
- Tensile Strength
- Assembly After Kinking Testing
- Dilator Tip Rollback Testing
- Radiopacity Testing
- Biocompatibility – Testing shows that the subject devices conform to the biocompatibility requirements based on its intended use. All evaluation criteria were met. The following biological effects were evaluated:
    - Cytotoxicity
    - Sensitization
    - Irritation/Intracutaneous Reactivity
    - Acute Systemic Toxicity
    - Material-mediated Pyrogenicity
- Sterilization
- Package integrity and stability
- Shelf-life

All predetermined acceptance criteria were met.

Conclusion:

The data included in this submission indicate that the subject devices do not raise new questions of safety or effectiveness compared to the predicate device (K851144), which supports a determination of substantial equivalence.