May 24, 2018

COOK Incorporated
Carly Powell
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, IN 47404

Re: K180756
Trade/Device Name: Safety Wire Guide Introducer
Regulation Number: 21 CFR§ 876.5470
Regulation Name: Ureteral Dilator
Regulatory Class: II
Product Code: EZN
Dated: March 21, 2018
Received: March 22, 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,

Joyce M. Whang -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: January 31, 2017
See *PRA Statement below.*

510(k) Number *(if known)*

K180756

Device Name

Safety Wire Guide Introducer

Indications for Use *(Describe)*

The Safety Wire Guide Introducer is used for antegrade placement of a safety wire guide prior to endourological procedures.

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
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"An agency may not conduct or sponsor, and a *person is not required to respond to,* a

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2.0 510(k) Summary

Safety Wire Guide Introducer
As required by 21 CFR 807.92
Date Prepared: May 23, 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) 339-2235
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Safety Wire Guide Introducer
Common Name:	Ureteral dilator
Classification Name:	Ureteral Dilator
Regulation, Class:	21 CFR §876.5470, Class II
Product Code, Panel:	EZN, Gastroenterology/Urology

Predicate Device:

The predicate device is Boston Scientific's 8/10 Dilator/Sheath Set, cleared for commercial distribution under 510(k) number K851144.

Device Description:

The Safety Wire Guide Introducer is used for antegrade placement of a safety wire guide prior to endourological procedures. The Safety Wire Guide Introducer includes an obturator and sheath. The radiopaque polyethylene obturator is 7.0 French, 25.7 cm in length, and has a 1 cm taper along the distal tip of the device. It can be inserted through the radiopaque polyethylene introducer sheath that is 12.0 French, 22.2 cm in length, and tapers 6 mm from the distal end of the device.

Indications for Use:

The Safety Wire Guide Introducer is used for antegrade placement of a safety wire guide prior to endourological procedures.

Comparison to Predicate Device:

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

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

- Dimensional Testing
- Tensile Strength
- Assembly After Kinking Testing
- Obturator/Sheath Tip Rollback Testing
- Radiopacity Testing
- Biocompatibility – Testing shows that the subject device conforms 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 device does not raise new questions of safety or effectiveness compared to the predicate device (K851144), which supports a determination of substantial equivalence.