



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 24, 2016

Cook Incorporated
Kara Kanorr
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K160891
Trade/Device Name: Ultrathane Endoureterotomy Stent Set
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: March 30, 2016
Received: March 31, 2016

Dear Kara Kanorr,

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K160891

Device Name

Ultrathane Endoureterotomy Stent Set

Indications for Use (Describe)

The device is intended for temporary internal drainage from the ureteropelvic junction to the bladder following dilation and/or incision of a stricture. Double pigtail ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. These stents may be placed using endoscopic, percutaneous, or open surgical techniques.

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

Ultrathane[®] Endoureterotomy Stent Set 21 CFR §807.92 Date Prepared: March 30, 2016

Submitted By:

Submission: Traditional 510(k) Premarket Notification
Applicant: Cook Incorporated
Contact: Kara Kanorr
Applicant Address: Cook Incorporated
750 Daniels Way
Bloomington, IN 47404
Contact Phone: (812) 339-2235 x104072
Contact Fax: (812) 332-0281

Device Information:

Trade Name: **Ultrathane[®] Endoureterotomy Stent Set**
Common Name: Stent, Ureteral
Classification Name: Ureteral Stent
Classification Regulation: 21 CFR §876.4620, Product Code FAD
Device Class/Classification Panel: Class II, Gastroenterology/Urology

Predicate Device:

The predicate device is the Retromax[™] Plus Endopyelotomy Stent cleared under 510(k) K924608.

Device Description:

The Ultrathane[®] Endoureterotomy Stent Set is comprised of a double pigtail endoureterotomy stent and coaxial positioner. The endoureterotomy stent body has a dual diameter design with a larger diameter section tapered to a smaller diameter section. This dual diameter option is available with a 9.5 French to 6.0 French taper or a 14.0 French to 7.0 French taper. The small diameter section has drainage holes along the stent body. The stent body working length is available in 18 to 30 centimeters. Sideports are located along the curl to allow for drainage. The stent (stent body and pigtails) is made of radiopaque polyurethane elastomer.

The coaxial positioner consists of a release sleeve and a stent positioner. The release sleeve is made of radiopaque tetrafluoroethylene. The release sleeve has a 10.0 French outer diameter and a 38 centimeter working length. The release sleeve is able to lock into the stent positioner via a compression fitting consisting of a connector cap and luer lock adapter. The stent positioner is made of polyethylene and has a distal stainless steel marker. The stent positioner has a 7.0 French outer diameter and a 46.1 centimeter working length. The stent positioner accepts a 0.038



inch wire guide.

The set will be supplied sterile and is intended for one-time use. The set is packaged in a peel-open pouch with a three-year shelf life.

Indications for Use:

The device is intended for temporary internal drainage from the ureteropelvic junction to the bladder following dilation and/or incision of a stricture. Double pigtail ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. These stents may be placed using endoscopic, percutaneous, or open surgical techniques.

Comparison to Predicate Device:

The proposed device has similar indications for use, methods of operation, and fundamental technological characteristics as the predicate device. Differences between the proposed device and the predicate device include dimensional variations, inclusion of a release sleeve, and material. Characteristics of the proposed device that differ from the predicate device are supported by testing.

Performance Data:

The following testing was performed in order to demonstrate that the proposed Ultrathane[®] Endoureterotomy Stent Set met applicable design and performance requirements.

- Tensile Strength – Testing shows the tensile force during proper clinical use should not fracture the Ultrathane[®] Endoureterotomy Stent Set materials and bonds. All predetermined acceptance criteria were met.
- Curl Retention (stent only) – Testing shows the curl retention during proper clinical use should retain the Ultrathane[®] Endoureterotomy Stent within the intended anatomy. Testing also shows the curl retention strength must allow for removal of the Ultrathane[®] Endoureterotomy Stent within the intended anatomy. All predetermined acceptance criteria were met.
- Magnetic Resonance (MR) – Testing shows that the proposed device is MR conditional based on defined, tested conditions. All predetermined acceptance criteria were met.
- Biocompatibility – Testing shows that the proposed device conforms with the biocompatibility requirements based on its intended use. All predetermined acceptance criteria were met.

Conclusion:

The results of these tests provide reasonable assurance that the Ultrathane[®] Endoureterotomy Stent Set will function as intended. The proposed device does not raise new questions of safety or effectiveness as compared to the predicate device.