March 26, 2018

Cook Incorporated
Karthik Pillai
Regulatory Science Specialist
750 Daniels Way P.O. Box 489
Bloomington, IN 47402

Re: K172017
Trade/Device Name: Black Silicone Filiform Double Pigtail Stent Set
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral stent
Regulatory Class: II
Product Code: FAD
Dated: February 16, 2018
Received: February 20, 2018

Dear Karthik Pillai:

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. However, you are responsible to determine that the medical devices you use as components in the kit 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. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172017

Device Name
The Black Silicone Filiform Double Pigtail Ureteral Stent Set

Indications for Use *(Describe)*
This product is used for temporary internal drainage from the ureteropelvic junction to the bladder. They are not intended to remain indwelling more than twelve months.

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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510(k) Summary

Black Silicone Filiform Double Pigtail Stent Set
21 CFR §876.4620
Date Prepared: June 30, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact:	Karthik Pillai
Email:	RegSubmissions@CookMedical.com
Contact Phone Number:	812-335-3575 x104929
Contact Fax Number:	812-332-0281

Device Information:

Trade Name:	Black Silicone Filiform Double Pigtail Ureteral Stent Set
Common Name:	Ureteral Stent
Classification Name:	Ureteral Stent
Regulation:	21 CFR §876.4620
Product Code:	FAD
Device Class:	II
Classification Panel:	Gastroenterology/Urology

Predicate Device:

The predicate device is Universa™ Firm Ureteral Stents and Stent Sets, cleared under 510(k) K161236 on January 27, 2017.

Device Description:

The Black Silicone Filiform Double Pigtail Stent Set is a sterile, single-use device. The stents are available with outside diameters of 6.0, 7.0, or 8.5 Fr and specified lengths ranging from 20 to 30 centimeters. The stents are flexible, tubular double pigtail stents constructed of radiopaque silicone rubber. Sideports extend along the body of the stent as

well as on the pigtails to provide drainage. The stents are secured in the urinary tract with pigtail loops on the proximal and distal ends. A braided tether for repositioning and removal of the device is located on the proximal pigtail (bladder end) of the stent. Along the stent are graduation marks to provide visualization during stent advancement and placement. The Black Silicone Filiform Double Pigtail Stent Set includes a stent, wire guide, a stent positioner with a lockable fitting, and a T-inserter. The lockable fitting on the proximal end of the stent positioner secures the position of the stent positioner on the wire guide and allows for one-pass placement of the stent. The Black Silicone Filiform Double Pigtail Stent Set is labeled for a 12-month indwell time; however, the tether should be removed after 14 days.

Intended Use:

This product is used for temporary internal drainage from the ureteropelvic junction to the bladder. They are not intended to remain indwelling more than twelve months.

Comparison to Predicate Device:

The Black Silicone Filiform Double Pigtail Ureteral Stent Set is substantially equivalent to the predicate device, the Universa™ Firm Ureteral Stents and Stent Sets, as described in K161236. The table below presents the similarities and differences between the devices for substantial equivalence purposes. The differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence and were developed using acceptable scientific methods for evaluation.

	Universa™ Firm Ureteral Stent and Stent Set (K161236)	**Black Silicone Filiform Double Pigtail Ureteral Stent Set (Subject of this submission)**
Indications for Use	Used for temporary internal drainage from the ureteropelvic junction to the bladder. Ureteral stents have been used to relieve obstruction in a variety of benign, malignant, and post-traumatic conditions. The stents may be placed using endoscopic, percutaneous, or open surgical techniques.	Used for temporary internal drainage from the ureteropelvic junction to the bladder. They are not intended to remain indwelling more than twelve months.
Maximum Indwell Time	12 months	Identical
Sterilization	Ethylene oxide	
Maximum Shelf Life	3 years	Identical

	Universa™ Firm Ureteral Stent and Stent Set (K161236)	**Black Silicone Filiform Double Pigtail Ureteral Stent Set (Subject of this submission)**
Principle Operation Components	• Double pigtail stent • Stent positioner • Wire guide	• Double pigtail stent • Stent positioner with lockable fitting • Wire guide • T-inserter
Dimensions		
Loop Diameter	13 mm - 20 mm	15 mm - 18 mm
Stent Outer Diameter	5 Fr - 8 Fr	6 Fr - 8.5 Fr
Stent Length	18 cm - 30 cm	20 cm - 30 cm
Pusher/Positioner	5 Fr and 7 Fr	7 Fr, 8 Fr, and 9 Fr
Materials		
Stent	Radiopaque Polycarbonate-based Polyurethane	Radiopaque Silicone Rubber
Stent Markings	Black Ink	White Ink
Tether	Tevdek® (Polyethylene Terephthalate)	Identical
Pusher/Positioner	Polyethylene Non-radiopaque or Vinyl	Identical
Pusher/Positioner Marker	Stainless Steel	Stainless Steel or Tungsten
Wire Guide	PTFE-coated Stainless Steel	Identical

Technological Characteristics:

The Black Silicone Filiform Double Pigtail Ureteral Stent Set was subjected to the following tests to assure reliable design and performance under the specified testing parameters:

1. Sterility
2. Packaging
3. Biocompatibility
4. Flow Rate
5. Retention Strength
6. Tensile Strength
7. Curl Restoration
8. Kink Radius
9. Radiopacity
10. MRI Testing

Conclusion:

The results of the testing provide reasonable assurance that the Black Silicone Filiform Double Pigtail Ureteral Stent Set has been designed such that it will function as intended. The subject device does not raise new questions of safety or effectiveness as compared to the predicate.