November 22, 2017

Cook Incorporated
Samuel Engelman
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K172278
Trade/Device Name: Firlit-Kluge Urethral Stent, Koyle Diaper Stent, Zaontz Urethral Stent
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: GBM
Dated: October 19, 2017
Received: October 20, 2017

Dear Samuel Engelman:

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)*

K172278

Device Name
Firlit-Kluge Urethral Stent

Indications for Use *(Describe)*

This device is used for stenting the urethra during hypospadias or epispadias repair and to allow postoperative drainage of the bladder in infants (29 days to less than 2 years old) and children (2 years old to less than 12 years old).

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 Paperwork Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

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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)*
K172278

Device Name
Koyle Diaper Stent

Indications for Use *(Describe)*
This device is used for stenting the urethra during hypospadias or epispadias repair and to allow postoperative drainage of the bladder in infants (29 days to less than 2 years old) and children (2 years old to less than 12 years old).

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)

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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)*

K172278

Device Name
Zaontz Urethral Stent

Indications for Use *(Describe)*
This device is used for stenting the urethra during hypospadias or epispadias repair and to allow postoperative drainage of the bladder in infants (29 days to less than 2 years old) and children (2 years old to less than 12 years old).

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)

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2.0 510(k) Summary

Firlit-Kluge Urethral Stent, Koyle Diaper Stent, and Zaontz Urethral Stent
21 CFR §807.92
Date Prepared: November 22, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Samuel Engelman
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x104340
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	**Firlit-Kluge Urethral Stent** **Koyle Diaper Stent** **Zaontz Urethral Stent**
Common Name:	Catheter, Urethral
Classification Name:	Urological catheter and accessories
Classification Regulation:	21 CFR §876.5130, Product Code GBM
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Device:

The predicate devices are the VPI-Fair Urethral Stent cleared under 510(k) K820313 and the Disposable Silicone Foley Catheter cleared under K130908.

Device Description:

The Firlit-Kluge Urethral Stent is constructed out of silicone tubing and a silicone ball. The stent tubing comes in both 8 French (Fr) and 10 French (Fr). The ball is located between the distal and proximal end of the stent tubing. The 8 Fr stent comes in lengths of 31, 40, and 50 cm. The 10 Fr stent comes in lengths of 31 and 50 cm.

The Firlit-Kluge Urethral Stent has one variation with additional sideports. This catalogue number has 8 Fr tubing and a length of 31cm. There are a total of 40 sideports.

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The Koyle Diaper Stent is constructed of C-Flex tubing and C-Flex suture funnel. The tubing is 50 cm in length and is available in diameters of 6 and 10 Fr. The tubing has four or eight distal sideports. The distal tip is open and rounded smooth; the proximal end is open. The suture funnel is bonded in between the distal and proximal tip. One version of the 6 Fr stent has ink marks from the distal tip to the suture funnel.

The Zaontz Urethral Stent is constructed from C-Flex tubing. The stent has two drainage sideports placed opposite of each other at the distal tip. The stent's proximal tip is flared and has four sideports. The stent is available in 6, 8, and 10 Fr diameter sizes and the length is 12 cm.

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

Indications for Use:

This device is used for stenting the urethra during hypospadias or epispadias repair and to allow postoperative drainage of the bladder in infants (29 days to less than 2 years old) and children (2 years old to less than 12 years old).

Comparison to Predicate Device:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate devices. Differences between the subject devices and the predicate devices are the indications for use, dimensional variations, sideports, and materials. Characteristics of the subject devices that differ from the predicate devices are supported by testing and analysis.

Performance Data:

The following testing was performed in order to demonstrate that the Firlit-Kluge Urethral Stent, Koyle Diaper Stent, and Zaontz Urethral Stent met applicable design and performance requirements.

- Biocompatibility

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- Sterilization Testing
- Packaging Testing
- Dimensional Verification Testing
- Tensile Testing
- Flow Rate Testing
- Accelerated Age Testing

Conclusion:

The results of these tests provide reasonable assurance that the Firlit-Kluge Urethral Stent, Koyle Diaper Stent, and Zaontz Urethral Stent will function as intended. The subject devices do not raise new questions of safety or effectiveness as compared to the predicate devices.