DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 28, 2017

Cook Incorporated
Minjin Choi
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47404

Re: K170010
Trade/Device Name: Salle Intraoperative Pyeloplasty Stent Set
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: July 14, 2017
Received: July 14, 2017

Dear Minjin Choi:

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,

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: January 31, 2017
See *PRA Statement below.*

51O(k) Number *(if known)*
K170010

Device Name
Salle Intraoperative Pyeloplasty Stent Set

Indications for Use *(Describe)*
This device is intended to establish and maintain nephrostomy and internal drainage following pyeloplasty for pediatric patients. This device is intended for patients 6 months and older.

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

Salle Intraoperative Pyeloplasty Stent Set

21 CFR §807.92

Date Prepared: December 30, 2016

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Minjin Choi
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x104901
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	**Salle Intraoperative Pyeloplasty 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:

- Primary predicate device:

  Expel™ Nephroureteral Drainage Stent with Twist-Loc™ Hub System (K141344)

- Secondary predicate device:

  Pediatric Ureteral Stent (K060673)

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Device Description:

The Salle Intraoperative Pyeloplasty Stent is a single-lumen ureteral stent inserted following pyeloplasty in order to provide internal and external drainage. It is a prolonged indwelling device not to exceed 4 weeks in the body.

The Salle Intraoperative Pyeloplasty Stent Set is comprised of a stent, wire guide, connecting tube, adaptor, and retention disc with pull tie. The Salle Intraoperative Pyeloplasty Stent is a double pigtail stent that advances from the renal pelvis to the bladder with a flexible extended portion that is brought out percutaneously through the kidney. The Salle stent is available in outer diameters of 4.0 or 4.7 French with working lengths of 12 to 18 cm. The stent's proximal pigtail forms in the renal pelvis, while the distal pigtail forms in the bladder. Drainage can occur internally (from the kidney to the bladder) or externally (from renal pelvis to the outside of the patient). The distal (bladder) pigtail coil is available in a multi-length stent configuration with drainage holes. The proximal (kidney) pigtail coil also contains sideports and ink marks to facilitate the visualization of accurate placement. The proximal end of the stent has an internal stylet which acts as a positioning stylet.

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 Salle Intraoperative Pyeloplasty Stent Set is intended to establish and maintain nephrostomy and internal drainage following pyeloplasty for pediatric patients. This device is intended for patients 6 months and older.

Comparison to Predicate Devices:

The Salle Intraoperative Pyeloplasty Stent Set and its primary predicate device, the Expel Nephroureteral Drainage Stent with Twist-Loc Hub System (K141344), are substantially equivalent in that these devices have similar intended uses, fundamental technological characteristics, and design. The modifications from the predicate device include:

- Indications for Use
- Stent material
- Placement method
- External end of stent

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The proposed Salle Intraoperative Pyeloplasty Stent Set is also similar in indications for use, dimensions, and methods of operation to the Pediatric Ureteral Stent (K060673). Differences between the proposed device and the predicate device include:

- Stent sizes
- Stent material
- Placement method
- External end of stent

Differences between the characteristics of the proposed device sets and the predicate devices are supported by testing.

Performance Data:

The biocompatibility evaluation for the Salle Intraoperative Pyeloplasty Stent Set was conducted in accordance with the FDA's U*se of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"* June 16, 2016 and *International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1 Evaluation and testing within a risk management process" (ISO 10993-1:2009).*

The following biocompatibility testing was successfully completed;

- Cytotoxicity
- Sensitization
- Intracutaneous
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity
- Implantation – 2 Week
- Implantation – 4 Week
- Subacute/Subchronic Toxicity
- Genotoxicity
- Toxicological Risk Assessment of Extractable Chemicals

A summary of the bench testing completed is detailed in Table 1.

Testing was successfully performed per Cook Inc.'s design control system in line with 21 CFR 820.30. The results from performance testing demonstrated that the subject device will remain sterile and will perform as intended for its 3 year shelf life.

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Table 1: Summary of the Bench Testing Performed

Test	Acceptance Criteria	Result
Retention Strength and Break Strength Testing (Simulated use – Time Zero and post aging)	**Retention Strength** The minimum retention strength shall be greater than or equal to 0.03 N, but less than or equal to 3.9 N (90% coverage, 90% confidence). **Break Strength** The minimum break strength shall be greater than 3.9 N (90% coverage, 90% confidence).	All acceptance criteria were met. Pass
Retention Strength and Break Strength Testing Following a 30 Day Artificial urine Soak (Simulated use – Time Zero and post aging)	**Retention Strength** The minimum retention strength shall be greater than or equal to 0.03 N, but less than or equal to 3.9 N (90% coverage, 90% confidence). **Break Strength** The minimum break strength shall be greater than 3.9 N (90% coverage, 90% confidence).	All acceptance criteria were met. Pass
Wire Guide Compatibility, Kink Radius, and Flow Rate and Leakage Post Kinking Testing	**Wire Guide Compatibility** The appropriate size wire guide shall pass through the inner lumen of each test article. **Kink Radius** The kink radius of each test article shall be less than 30 mm based on worst-case analysis. **Flow Rate and Leakage Post Kinking** Flow rate performed for characterization purposes only. If leakage detected, test article deemed a failure.	All acceptance criteria were met. Pass
Radiopacity Testing	Testing Per ASTM F640-12[1] The Salle Stent is visible under fluoroscopy. Visibility of the Salle Stent is equal to or greater than the visibility of the user-defined standard.	All acceptance criteria were met. Pass
MR Testing	**Magnetically Induced Displacement Force** Testing per ASTM F2052-15[2] Deflection Angle $<45^{o}$ **Magnetically Induced Torque** Testing per ASTM F2213-06[3] (2011) $\tau_{mag} < \tau_{grav}$ **Electrical Conductivity** <1 S/m **MR Image Artifacts** Testing per ASTM F2119-07[4] (2013) For information only.	All acceptance criteria were met. Pass

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Conclusion:

The results of these tests support a conclusion that the Salle Intraoperative Pyeloplasty Stent Set will perform as intended. The proposed device set does not raise new questions of safety or effectiveness as compared to the predicate devices.

1 ASTM F640-12 Standard Test Methods for Determining Radiopacity for Medical Use

2 ASTM F2052-15 Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment.

3 ASTM F2213-06 (2011) Standard test method for measurement of magnetically induced torque on passive implants in the magnetic resonance environment.

4 ASTM F2119-07 (2013) Standard test method for evaluation of MR image artifacts from passive implants