Cook Incorporated  
Minjin Choi  
Regulatory Affairs Specialist  
750 Daniels Way  
Bloomington, IN 47404

Re: K190903  
Trade/Device Name: Lawson Retrograde Nephrostomy Wire Puncture Set  
Regulation Number: 21 CFR  
Regulation Name: None  
Regulatory Class: Unclassified  
Product Code: LJE  
Dated: November 15, 2019  
Received: November 18, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm) identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark R. Kreitz -S

for Jessica Nguyen, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

Used to gain precise percutaneous access to the kidney by means of controlled fine wire puncture from within the collecting system for patients aged 12 years 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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2.0 510(k) Summary

Lawson Retrograde Nephrostomy Wire Puncture Set
21 CFR §807.92
Date Prepared: November 15, 2019

Submitted By:
Submission: Traditional 510(k) Premarket Notification
Applicant: Cook Incorporated
Primary Contact: Minjin Choi
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Device Information:
Trade Name: Lawson Retrograde Nephrostomy Wire Puncture Set
Common Name: Nephrostomy Catheter
Classification Name and Number: None
Primary Product Code: LJE (Catheter, Nephrostomy)
Regulatory Class: Unclassified
Classification Panel: Gastroenterology/Urology

Predicate Device:
The predicate device is the Percutaneous Retrograde Nephrostomy Puncture Set (K833762), cleared for market by the FDA on February 10, 1984.
Device Description:

The Lawson Retrograde Nephrostomy Wire Puncture Set is used to gain percutaneous access to the kidney by means of a controlled fine wire puncture from within the collecting system.

The Lawson Retrograde Nephrostomy Wire Puncture Set is composed of the tip-deflecting wire guide, catheter, sheathed puncture wire, coaxial needle assembly (inner and outer needle cannulae) and working wire guide. The tip-deflecting wire guide is used to direct the catheter into the desired calyx in a retrograde manner using standard access techniques, followed by exchange of the deflecting wire with the sheathed puncture wire. To initiate percutaneous nephrostomy access, the puncture wire is unsheathed and advanced from the catheter through the kidney towards the patient’s flank and through the skin. The coaxial needle assembly is then advanced over the puncture wire and into the renal collecting system, and then the puncture wire and inner needle cannula are removed to allow a working wire guide to be placed through the outer needle cannula.

- The tip-deflecting wire guide has a three-ring handle which twist-locks with the catheter. The tip-deflecting wire guide is made from stainless steel and is available in an outer diameter of 0.045 in.
- The catheter is available in an outer diameter of 7 Fr with a length of 82.5 cm and made of braided nylon tubing. The sheathed puncture wire can interlock with the proximal portion of the catheter.
- The sheath is made of radiopaque TFE tubing which extends 1 cm from the catheter when locked together. The sheath is available in an outer diameter of 3 Fr with a length of 85 cm.
- The puncture wire is made of stainless steel with a plastic pin vise handle. The puncture wire has an outer diameter of 0.43 mm with a length of 145 cm.
- The needle set has a 22 gage inner needle that is 22.5 cm in length with the outer needle being 18 gage and 14 cm in length.
- The working wire guide is made of stainless steel and is 0.97 mm in diameter and 145 cm in length.
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 Lawson Retrograde Nephrostomy Wire Puncture Set is used to gain precise percutaneous access to the kidney by means of controlled fine wire puncture from within the collecting system for patients aged 12 years and older.

**Comparison to Predicate Devices:**
The Lawson Retrograde Nephrostomy Wire Puncture Set and the predicate device, Percutaneous Retrograde Nephrostomy Puncture Set (K833762), are substantially equivalent in that they have the same intended use. Furthermore, the devices have nearly identical methods of operation, design, and dimensions. The modifications from the predicate device includes:

- Indications for Use
- Tip-Deflecting Wire (Dimension)
- Catheter (Dimension and Materials)
- Sheath (Materials)

Differences between the characteristics of the subject device and the predicate device are supported by testing.

**Performance Data:**
The following testing was performed in order to demonstrate that the subject device, Lawson Retrograde Nephrostomy Wire Puncture Set, met applicable design requirements.

- Biocompatibility
- Compatibility
- Dimensional
- Tensile Strength
  - Hub-to-Shaft Bond of Catheter, Sheath, Stylet, and Needles
• Tip-to-Shaft Bond of Catheter
• Distal Tip of Deflecting Wire
• Shaft of Puncture Wire

• Radiopacity
• Shelf Life following Accelerated Aging to Three-year Real-Time Equivalency
• Packaging, Sterility and Stability

**Conclusion:**
All predetermined acceptance criteria of the testing were met. Therefore, the results of these tests support a conclusion that the Lawson Retrograde Nephrostomy Wire Puncture Set will perform as intended and support a determination of substantial equivalence to the predicate device.