DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 7, 2017

Cook Incorporated
Carly Powell
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K162109
Trade/Device Name: Kwart Retro-Inject™ Stent Set
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: May 24, 2017
Received: May 25, 2017

Dear Carly Powell:

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.

510(k) Number *(if known)*

K162109

Device Name

Kwart Retro-Inject™ Stent Set

Indications for Use *(Describe)*

Used for retrograde injection during Extracorporeal Shock Wave Lithotripsy (E.S.W.L.) and leaving an indwelling ureteral stent post-E.S.W.L.

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

Kwart Retro-Inject™ Stent Set
21 CFR §807.92
Date Prepared: June 6, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Registration Number:	1820334
Contact:	Carly Powell
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x104913
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	**Kwart Retro-Inject™ 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 primary predicate device is the Contour™ and Contour VL™ Injection Ureteral Stent Set cleared under 510(k) K010002. The secondary predicate device is the Boston Scientific Hydrogel Coated Percuflex Drainage Catheter cleared under K924608.

Device Description:

The Kwart Retro-Inject™ Stent Set is intended to be marketed as a set with multiple components. The set is comprised of a double pigtail ureteral stent with tether, inserter, release sleeve, wire guide, and an adapter. The stent is available as a specified length or a multi-length stent with or without hydrophilic coating. The specified lengths are 22, 24, 26, and 28 centimeters with outer diameters of 4.7, 6, and 7 French. The multi-length stent offers a range of 22-32 centimeters with outer diameters of 4.7, 6, 7, and 8.2 French. Both specified and multi-length stents have drainage holes along the kidney loop, and continuing along the stent body extending from the kidney. However, the bladder pigtail and 15 centimeters of the stent body extending from the bladder loop do not have drainage holes. The bladder pigtail has a polyethylene terephthalate tether attached. In addition, both stent types are constructed of radiopaque polyurethane elastomer and

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have radiopaque ink marks to aid in stent placement. The stents accept either a 0.035 or a 0.038 inch wire guide.

The inserter is made of radiopaque polyurethane and has radiopaque ink markers. The inserter is available in outer diameters of 4.5, 5, or 6 French with a 70 centimeter working length. The inserter accepts a 0.038 inch wire guide. A female luer lock to connector cap adapter may be attached on the inserter to provide injection. The release sleeve is made of radiopaque plasticized polyvinylchloride. The release sleeve has an 8 or 10 French outer diameter and a 38 centimeter working 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 device is used for retrograde injection during Extracorporeal Shock Wave Lithotripsy (E.S.W.L.) and leaving an indwelling ureteral stent post- E.S.W.L.

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 devices include indwell time, design specifications, dimensions, and materials. Characteristics of the proposed device that differ from the predicate devices are supported by testing.

Performance Data:

The following testing was performed in order to demonstrate that the proposed Kwart Retro-Inject™ Stent Set met applicable design and performance requirements.

- Retention Strength and Break Strength – Retention strength testing shows the curl retention during proper clinical use should retain the Kwart Retro-Inject™ Stents within the intended anatomy. Testing also shows the curl retention strength must allow for removal of the Kwart Retro-Inject™ Stents from the intended anatomy. Break strength testing evaluates the tensile forces to break the curl and shaft of the Kwart Retro-Inject™ Stents. Additional retention strength and break strength testing was conducted following a 30-day artificial urine soak and after accelerated aging to the real-time equivalent of three years both with and without a 30-day urine soak. All predetermined acceptance criteria were met.
- Dynamic Frictional Force – Testing characterized the dynamic frictional force acting on the outer surface of the Kwart Retro-Inject™ Stents. The evaluation included the dynamic

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frictional force testing of both the hydrophilically coated stents and the uncoated stents at time zero and after accelerated aging to the real-time equivalent of three years.

- Radiopacity- Testing assessed the radiopacity of the Kwart Retro-Inject Stent™ by subjecting it to a comparative fluoroscopic evaluation. Testing was conducted on the stents at time zero.
- Gravity Flow Rate – Testing characterized the gravity flow rate of the Kwart Retro-Inject™ Stents. The evaluation was conducted on the stents at time zero.
- 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 Kwart Retro-Inject™ Stent Set will perform as intended. The proposed device does not raise new questions of safety or effectiveness as compared to the predicate devices.