August 23, 2018

Cook Incorporated
Chelsea Woods
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, Indiana 47402

Re: K173657
Trade/Device Name: Radiance™ Clear Sharklet® Silicone Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: Class II
Product Code: EZL
Dated: July 23, 2018
Received: July 24, 2018

Dear Chelsea Woods:

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 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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.

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 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,

Glenn B. Bell -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)*

K173657

Device Name
Radiance™ Clear Sharklet® Silicone Foley Catheter

Indications for Use *(Describe)*

This device is intended for providing drainage of urine from the urinary tract.

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

Radiance™ Clear Sharklet® Silicone Foley Catheter
21 CFR §807.92
Date Prepared: August 23, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Chelsea Woods
Secondary Contact:	Andrew Breidenbach
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Primary Contact Phone:	(812) 339-2235 x104707
Secondary Contact Phone:	(812) 339-2235 x105147
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	**Radiance™ Clear Sharklet® Silicone Foley Catheter**
Common Name:	Catheter, Retention Type, Balloon
Classification Name:	Urological Catheter and accessories
Classification Regulation:	21 CFR 876.5130, Product Code EZL
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Device:

The predicate device is the Well Lead Silicone and Latex Foley Catheters cleared under 510(k) Premarket Notification number K082815.

Device Description:

The Radiance™ Clear Sharklet® Silicone Foley is identified as a balloon retention type catheter and is supplied sterile for single-use. It is a two-way silicone Foley catheter manufactured in 14.0, 16.0 and 18.0 French sizes with an effective working length of 34 centimeters. One lumen is used for drainage and the other lumen for inflation and deflation of the balloon. Sterile media is used to inflate and deflate the balloon. The proximal end of the drainage lumen has a funnel for connection to a drainage collection

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device. The proximal end of the inflation lumen has a check valve for connection to a syringe for inflation. The distal end has two drainage eyes placed opposite each other which allow drainage. The shaft has the Sharklet® micro-pattern molded into the outer surface.

Indications for Use:

This device is intended for providing drainage of urine from the urinary tract.

Comparison to Predicate Device:

The subject device has similar indications for use, methods of operation, and fundamental technological characteristics as the predicate devices. Differences between the subject device and the predicate device include a difference in indications for use, surface modifications, and dimensions. Characteristics of the subject device that differ from the predicate device are supported by testing and analysis.

Performance Data:

The following testing was performed in order to demonstrate that the proposed Radiance™ Clear Sharklet® Silicone Foley Catheter met applicable design and performance requirements in accordance with FDA recognized consensus standard ASTM F623-99, *Standard Specification for Foley Catheters*.

- Flow Rate through Drainage Lumen
- Balloon Integrity
- Inflated Balloon Response to Traction
- Balloon Volume Maintenance
- Dimensional Verification
- Balloon Deflation Reliability

The following testing, in addition to those in ASTM F623-99, was performed in order to support the safety of the catheter's micropattern:

- Friction Testing: Devices were pulled horizontally across a silicone surface and frictional forces were recorded to calculate a coefficient of kinetic friction. This was performed on a 2-way silicone Foley catheter control device as well as the Radiance™ Clear Sharklet® Silicone Foley Catheter and the results were

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compared. The coefficient of kinetic friction for the Radiance™ Clear Sharklet® Silicone Foley Catheter was less than the control.

- Ovine Study: The Radiance™ Clear Sharklet® Silicone Foley Catheter and a 2-way silicone Foley catheter control device were each placed in six sheep for an indwell time of one month. The sheep were subsequently euthanized, a necropsy performed, and tissues excised for gross evaluation and histological processing. A comparison of the data revealed similar responses between the tested devices.

Additional accelerated aged performance testing, biocompatibility, and sterility testing were performed to demonstrate the subject device is appropriate for its intended use.

Conclusion:

The results of these tests provide reasonable assurance that the Radiance™ Clear Sharklet® Silicone Foley Catheter will function as intended. The subject device does not raise new questions of safety or effectiveness as compared to the predicate device.