September 28, 2018

Cook Incorporated
Rebecca Odulio (Li-Chun-Liu)
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K180216
Trade/Device Name: Seidmon Antegrade AQ Stent Set
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: September 7, 2018
Received: September 10, 2018

Dear Rebecca Odulio (Li-Chun-Liu):

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,

Mark R. Kreitz -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180216

Device Name
Seidmon Antegrade AQ Stent Set

Indications for Use *(Describe)*
The Seidmon Antegrade AQ Stent is intended for internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent as well as providing external drainage in patients age 18 years and older when treated as adults.

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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Section 2.0 510(k) Summary

Seidmon Antegrade AQ® Stent Set
(21 CFR §807.92)
Date Prepared: September 27, 2018

Submitted By:

Applicant:	Cook Incorporated
Contact Information:	Rebecca Odulio (Li-Chun Liu) Andrew Breidenbach
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone Number:	(812) 335-3575
Contact Fax Number:	(812) 332-0281

Device Information:

This Submission:	Traditional 510(k) Premarket Notification
Device Name:	Seidmon Antegrade AQ Stent Set
Common Name:	Ureteral Stent
Classification Number:	21 CFR §876.4620
Classification Name:	Ureteral Stent
Product Code:	FAD
Product Code Name:	Stent, Ureteral
Regulatory Class:	Class II

Predicate Device:

Expel Nephroureteral Drainage Stent with Twist-Loc Hub System (K141344) is the predicate device for the Seidmon Antegrade AQ Stent Set.

Device Description:

The Seidmon Antegrade AQ Stent Set contains a nephroureteral stent with hydrophilic coating, a Luer lock drainage adapter, and a Peel-Away Introducer. The stent tubing is made of radiopaque polyurethane and is provided in 6.0 French diameter with 50 centimeters in overall length (28 centimeters ureteral working length). The Luer lock drainage adapter is to be used with a drainage bag to provide the external drainage. The Peel-Away Introducer consists of a polyethylene dilator and a tetrafluoroethylene sheath,

which is used to facilitate percutaneous placement of the nephroureteral stent. The dilator is provided in 8.0 French diameter and 37 centimeters length. The sheath is provided in 10.0 French diameter and with 32 centimeters working length.

Indications for Use:

The Seidmon Antegrade AQ Stent Set is intended for internal drainage from the ureteropelvic junction to the bladder while maintaining external access to the stent as well as providing external drainage in patients age 18 years and older when treated as adults.

Comparison to Predicate:

The subject device has similar indications for use, methods of operation, and fundamental technological characteristics as the predicate. The differences between the subject device and the predicate device include language used in indications for use, minor dimensional variations, materials, indwelling time, device design features, and accessories provided. Characteristics of the subject device that differ from the predicate device are supported by testing. The subject device does not raise new questions of safety or effectiveness as compared to the predicate device.

Technological Characteristics:

The following tests have been conducted to demonstrate that the Seidmon Antegrade AQ Stent Set met applicable design and performance requirements.

- Sterilization and EO Residuals
- Packaging and Distribution
- Biocompatibility
- Dimensional Verification and Compatibility
- Pigtail Restoration/Recovery
- Curl Retention
- Tensile
- Lubricity
- Functional Use Flow Rate and Liquid Leakage
- Radiopacity
- Magnetic Resonance (MR) Imaging Safety
- Shelf Life/Stability

Conclusion:

All predetermined acceptance criteria of the testing were met. Therefore, the results of these tests support a conclusion that the subject device performs as intended and support a determination of substantial equivalence to the predicate device.