March 28, 2018

Wilson-Cook Medical, Inc.
Ashley Howard
Specialist I - Regulatory Affairs
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K171969
Trade/Device Name: Web II Memory Extraction Basket or Memory II Double Lumen Extraction Basket, Memory 5 Fr. Soft Wire Baskets or Memory Helical Stone Extractor, Memory Eight Wire Baskets or Memory Hard Wire Baskets, Fusion Wire Guided Extraction Basket, Non-Lithotripsy Extraction Basket
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: LQR
Dated: February 13, 2018
Received: February 14, 2018

Dear Ashley Howard:

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.

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.

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,

Joyce M. Whang -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)*

K171969

Device Name

Web II Memory Extraction Basket or Memory II Double Lumen Extraction Basket, Memory 5 Fr. Soft Wire Baskets or Memory Helical Stone Extractor, Memory Eight Wire Baskets or Memory Hard Wire Baskets, Fusion Wire Guided Extraction Basket, Non-Lithotripsy Extraction Basket

Indications for Use *(Describe)*

Endoscopic removal of stones in the biliary system and foreign bodies.

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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COOK ENDOSCOPY
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Non-Lithotripsy Extraction Basket
510(k) Premarket Notification
June 30, 2017

Applicant Information

Applicant:	Wilson-Cook Medical, Inc. / Cook Endoscopy 4900 Bethania Station Road Winston-Salem, North Carolina 27105
Contact:	Ashley Howard, Specialist I – Regulatory Affairs
Phone:	(336) 744-0157 ext. 6174
Fax:	(336) 201-5994

Device Information

Trade Name:	Web II Memory Extraction Basket or Memory II Double Lumen Extraction Basket, Memory 5 Fr. Soft Wire Baskets or Memory Helical Stone Extractor, Memory Eight Wire Baskets or Memory Hard Wire Baskets, Fusion Wire Guided Extraction Basket, Non-Lithotripsy Extraction Basket
Common Name:	Dislodger, Stone, Biliary
Classification Name:	Biliary Catheter and Accessories
Regulation Number:	21 CFR 876.5010
Product Code:	LQR
Device Class:	Class II
Review Panel:	Gastroenterology-Urology

Predicate Device

Name:	Wilson-Cook Stone Extractor
510(k) Number:	K851965
Date:	Cleared July 29, 1985

Device Description

The Non-Lithotripsy Extraction Basket is a sterile, single use device compatible with the accessory channel of endoscopes. The device consists of basket, catheter, and handle components. The basket component is constructed of monofilament or multifilament metal wires joined at the distal and proximal ends, and is advanced out of and retracted into the single or double lumen polytetrafluoroethylene catheter sheath using the handle component's actuator. The device is not compatible with any mechanical lithotripter.

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Intended Use
Endoscopic removal of stones in the biliary system and foreign bodies.

Comparison to Predicate Device
The Non-Lithotripsy Extraction Basket has the same principles of operation and fundamental technologies as the predicate device. Changes to the subject device include labeling to incorporate the addition of Instructions for Use with contraindications, dimensions, materials, handle configuration, and an expanded indication for use. These changes do not raise new questions of safety or effectiveness.

Performance Data and Non-Clinical Testing
Performance testing consisting of sterilization, shelf life, biocompatibility, and non-clinical bench testing demonstrate that the Non-Lithotripsy Extraction Basket meets the performance criteria required to fulfill the intended use of the device. The following summarizes the non-clinical bench testing conducted:

- Stone and Foreign Body Capture Testing
- Tensile Testing
- Flexibility Testing
- Post-Aging Functional Testing

Conclusion
We believe the risks associated with the modifications to the subject device were adequately addressed through our Design Control Processes and do not affect safety or effectiveness of the device. The information and data contained in this notification supports a determination of substantial equivalence.