October 30, 2018

Wilson-Cook Medical, Inc.
Tiffanny A. Thomas
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K182381
Trade/Device Name: Wilson-Cook Mini Basket
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: LQR
Dated: August 30, 2018
Received: August 31, 2018

Dear Tiffanny A. Thomas:

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,


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)*
K182381

Device Name
Wilson-Cook Mini Basket

Indications for Use *(Describe)*
Used for endoscopic removal of biliary stones, pancreatic stones, 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.**

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

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**Submitted By:**

| | |
|---|---|
| Submission: | Traditional 510(k) Premarket Notification |
| Applicant: | Wilson-Cook Medical, Inc. / Cook Endoscopy |
| Contact: | Tiffanny A. Thomas |
| Applicant Address: | Wilson-Cook Medical, Inc. / Cook Endoscopy<br>4900 Bethania Station Road<br>Winston-Salem, North Carolina 27105 |

**Contact Phone Number:** (336) 744-0157 ext.396680
**Contact Fax Number:** (336) 201-5994

**Device Information**

| | |
|---|---|
| Trade Name: | Wilson-Cook Mini 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: | Non-Lithotripsy Extraction Basket |
| 510(k) Number: | K171969 |
| Date: | Cleared March 28, 2018 |

**Device Description**

The Wilson-Cook Mini Basket Extraction Basket is a sterile, single use device used through the accessory channel of endoscopes. The device consists of basket, catheter, and handle components. The basket component is constructed of monofilament metal wires and a helical design. The catheter is 200 cm in total length with a working length of 182 cm and 5 Fr diameter. The catheter is composed of Polytetrafluoroethylene (PTFE). The handle is a pin-vice design composed of polycarbonate with an acetal side arm fitting. The device is not compatible with any mechanical lithotripter.

**Intended Use**

Used for endoscopic removal of biliary stones, pancreatic stones, and foreign bodies.

**Comparison to Predicate Device**
The Wilson-Cook Mini Basket Extraction Basket has the same principles of operation, direct patient contacting materials and fundamental technology as the predicate device. The modifications to the subject device include a more specific intended use, a smaller catheter diameter, dimensional changes to the basket and material change on the injection hub/side arm fitting. These changes do not raise new questions of safety or effectiveness.

**Summary of Non-Clinical Testing**
The following performance testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

- Stone and Foreign Body Capture Testing
- Tensile Testing
- Functional Testing
- Shelf Life Testing

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process" and per ISO 10993-1:2009, *Biological evaluation of medical devices- Evaluation and testing within risk management process.*

**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.