December 13, 2019

Wilson-Cook Medical Inc. /Cook Endoscopy
Theresa de Prat
Regulatory Affairs Specialist II
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K193344
Trade/Device Name: Tri-Ex Extraction Balloon with Multiple Sizing
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: GCA
Dated: December 2, 2019
Received: December 3, 2019

Dear Theresa de Prat:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter, Jr.
Assistant Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K193344

Device Name
Tri-Ex Extraction Balloon With Multiple Sizing

Indications for Use *(Describe)*
This device is used for endoscopic removal of biliary stones and for contrast injection.

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."

510(k) Summary

Name: Wilson-Cook Medical, Inc. /Cook Endoscopy
Address: 4900 Bethania Station Road
Winston-Salem, North Carolina 27105
Phone: (336) 744-0157
Fax: (336) 201-5994

Contact; Theresa de Prat, Regulatory Affairs Specialist II
Tiffanny A. Thomas, Global Regulatory Affairs Specialist

Date: December 2, 2019

Trade Names: Tri-Ex Extraction Balloon with Multiple Sizing

Common Name: Extraction Balloon

Classification Name: Biliary Catheter and Accessories

21 CFR §876.5010, GCA, Class II

Predicate Devices: Tri-Ex Extraction Balloon K170292, cleared 9/20/2017

Intended Use: This device is used for endoscopic removal of biliary stones and for contrast injection.

Device Description:
The subject extraction balloon is comprised of a latex balloon mounted at the distal end of a nylon catheter with three internal lumens. The balloon can be inflated to three diameter sizes, 8.5 mm, 12 mm and 15 mm. Radiopaque bands placed at the distal and proximal ends of the balloon provide fluoroscopic visualization of the balloon location. The catheter length is 275 cm with a diameter of 6.6 Fr. The three lumens correspond to a balloon inflation port, a wire guide port and an injection port. The hubs on the respective lumens are color-coded white, purple, and gray. A stopcock is included at the proximal end of the balloon inflation port to control air movement into or out of the balloon.

Substantial Equivalence:
A minor design change was made to the predicate Tri-Extraction Balloon with Multiple sizing cleared to market via K170292. This modification was a material change to the radiopaque markers.

Performance Data:
Performance testing consisting of non-clinical bench testing demonstrates the subject device met the performance requirements to fulfill the intended use. This testing provides reasonable assurance that the subject device will function as intended. The subject device does not raise new questions of safety or effectiveness as compared to the predicate device.

Summary of non-clinical testing:
The following non-clinical testing was conducted to demonstrate the performance of the subject device and confirms that the subject device performs as intended.

- Functional Testing/ Design Verification Testing
- Biocompatibility Assessment
- Fluoroscopic Visibility

Conclusion:
We believe that the subject device is substantially equivalent to the predicate device with respect to intended use, key operating principles, materials of construction, and technological characteristics. We consider the risks associated with the modifications to the subject devices to have been adequately addressed through our design control processes and do not affect the safety or effectiveness of the devices.