February 27, 2020

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

Re: K200247
Trade/Device Name: Fusion Quattro Extraction Balloon
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: GCA
Dated: January 30, 2020
Received: January 31, 2020

Dear Tiffanny 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/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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200247

Device Name
Fusion Quattro Extraction Balloon

Indications for Use *(Describe)*
This device is used for endoscopic removal of stones in the biliary system 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.

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"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: Tiffanny A. Thomas, Global Regulatory Affairs Specialist
Theresa de Prat, Regulatory Affairs Specialist II

Date: January 30, 2020

Trade Names: Fusion Quattro Extraction Balloon

Common Name: Extraction Balloon

Classification Name: Biliary Catheter and Accessories

21 CFR §876.5010, GCA, Class II

Predicate Devices: Fusion Quattro Extraction Balloons XL K063677, cleared January 5, 2007

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

Device Description:

The subject device is composed of a latex balloon mounted at the distal end of a nylon triple lumen catheter. The balloon can be inflated to four sizes: 8.5 mm, 10 mm, 12 mm, and 15 mm diameters. Radiopaque bands are placed on the catheter to provide fluoroscopic visualization of the catheter and balloon location. The nylon catheter length is 200 cm with a diameter of 6.6 Fr. There is an injection port on the catheter either above the balloon or below the balloon depending on the device model. The catheter also has black ink markings for direct visualization.

Substantial Equivalence:

A minor design change was made to the predicate Fusion Quattro Extraction Balloon XL cleared to market via K063677. The modification is a design change to include a balloon with inflation diameters of 8.5 mm, 10 mm, 12 mm, and 15 mm. The modification does not result in a change of intended use. Both the subject device and the predicate device are used for endoscopic removal of stones in the biliary system and for contrast injection.

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.

- Design Verification Testing
- Dimensional Verification
- Functional Testing
- 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 device to have been adequately addressed through our Design Control Processes, evaluated through a well-established method, and do not affect the safety or effectiveness of the device.