DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 20, 2016

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

Re: K160170
Trade/Device Name: Lehman Manometry Catheter
Regulation Number: 21 CFR§ 876.1725
Regulation Name: Gastrointestinal Motility Monitoring System
Regulatory Class: II
Product Code: FFX
Dated: June 6, 2016
Received: June 8, 2016

Dear Doris A. Hawks:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

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)*
K160170

Device Name
Lehman Manometry Catheter

Indications for Use *(Describe)*
This device is used for motility studies in the common bile duct, pancreatic duct, Sphincter of Oddi and duodenum.

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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510(k) Summary

Name: Wilson-Cook Medical, Inc. / Cook Endoscopy
Address: 4900 Bethania Station Road
Winston-Salem, North Carolina 27105
Phone: (336) 744-0157 ext. 6293
Fax: (336) 201-5994
Contact: Doris A. Hawks, Global Regulatory Affairs Specialist
Date: February 12, 2016

Device Name

Trade Name: Lehman Manometry Catheter
Common Name: Motility Catheter
Classification Name: System, Gastrointestinal Motility (Electrical)
21 CFR 876.1725, FFX, Class II

Predicate Device

Wilson-Cook Biliary Motility Catheter, k900058, cleared July 27, 1990

Intended Use

This device is used for motility studies in the common bile duct, pancreatic duct, Sphincter of Oddi and duodenum.

Device Description

The Lehman Manometry Catheter is a modification to the Wilson-Cook Biliary Motility Catheter currently cleared to market via 510k k900058 by Wilson-Cook Medical, Inc. The modified manometry catheter is compatible with a .018” inch wire guide and available in a 200 cm length with a 5 mm short tip or 15 mm long tip configuration. The catheter features include 1 mm marks at the distal end that provide reference points to the .023” inch perfusion and aspiration side ports and to indicate movement of the catheter while in use. The proximal end consists of three lumen color coded leads that provide access to the side ports and wire guide lumen. The red is designated to the proximal side perfusion port, the yellow is for the distal side perfusion port and the green leads to the middle aspiration or through the end of catheter wire guide ports.

Substantial Equivalence

Minor design changes were made to the predicate device cleared to market via k900058. These changes include modifications as follows: side port diameter, lead colors, additional (center) side ports; additional print marks, proximal and distal side port ink color; reusable to disposable; wire guide compatible and catheter tip length. The modified device is substantially equivalent to the predicate with respect to the intended use, key operating mechanics, materials and the technological characteristics.

Performance Data

The Risk Analysis was completed to access the impact of modifications to the cleared device using the Design Failure Modes, Effects and Criticality Analysis (DFMECA) method. Design verification and/or validation testing was performed as a result of this risk analysis assessment. Results from design validation and/or verification testing provide reasonable assurance that the modifications to the device do not raise any new questions of safety or effectiveness.

Conclusion

We believe risks associated with the modifications to the subject device to be adequately addressed through our Design Control Processes. We believe the proposed device to be substantially equivalent to the named predicate in terms of its intended use, performance characteristics tested.