DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 27, 2017

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

Re: K162142
Trade/Device Name: Accessory Irrigation Adapter
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODC
Dated: March 20, 2017
Received: March 21, 2017

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. 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,

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)*
K162142

Device Name
Accessory Irrigation Adapter

Indications for Use *(Describe)*
Used for introduction of irrigation fluid into the gastrointestinal tract through the endoscope working channel.

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."

Summary

Name:	Wilson-Cook Medical, Inc. /Cook Endoscopy
Address:	4900 Bethania Station Road Winston-Salem, North Carolina 27105
Phone:	(336) 744-0157 (x6518)
Fax:	(336) 201-5994
Contact:	Theresa de Prat, Regulatory Affairs Specialist II
Date:	July 29, 2016
Trade Name:	Accessory Irrigation Adapter
Common Name:	Accessory Irrigation Adapter
Classification Name:	Gastroenterology-Urology Endoscope and accessories (21 CFR §876.1500, Product Code ODC)
Predicate Device:	Scope Introducer, K093329, February 16, 2010
Description of the Device:	The Accessory Irrigation Adapter is a non-sterile device that is compatible with endoscopes with a maximum working channel of 2.2 mm. The Accessory Irrigation Adapter is approximately 2 inches long.
Intended Use:	The Accessory Irrigation Adapter is intended for introduction of irrigation fluid into the gastrointestinal tract through the endoscope working channel.
Technological Characteristics:	Both the subject device and the predicate device consist of a female luer adapter with a cannula. The subject device is comprised of a stainless steel cannula and a polypropylene luer. The predicate device is comprised of stainless steel. Both the predicate and the subject device can be inserted into a biopsy cap on an endoscope working channel and the user is then able to irrigate through the adapter.
Substantial Equivalence:	The Accessory Irrigation Adapter (subject device) is substantially equivalent to the Scope Introducer (predicate device) in that it has same intended use (more limited), method of operation, and fundamental technological characteristics (same materials for the barrel portion, and the same operational principle).

Traditional 510(k): Accessory Irrigation Adapter

Performance Data: Performance testing consisting of non-clinical bench testing demonstrates that the Accessory Irrigation Adapter met the performance requirements to fulfill the intended use of the device. The testing establishes that functional user requirements (able to insert through biopsy cap, able to irrigate through adapter, able to remove the adapter from working channel) were met after accelerated aging of the subject device. The results of this testing provide reasonable assurance that the Accessory Irrigation Adapter will function as intended over the shelf life of the product. The subject device does not raise new questions of safety or effectiveness as compared to the predicate device.

Conclusion: The Accessory Irrigation Adapter (subject device) is substantially equivalent to the predicate device.