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

July 31, 2017

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

Re: K171607
Trade/Device Name: Bronchi and Gastrointestinal Cytology Brush
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDX
Dated: May 31, 2017
Received: June 1, 2017

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,

Joyce M. Whang -S

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)*

K171607

Device Name
Bronchi and Gastrointestinal Cytology Brush

Indications for Use *(Describe)*
This device is used to collect cells from the bronchi or upper and lower gastrointestinal tracts.

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.

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WINSTON-SALEM, NC 27105 U.S.A.
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009. 510(k) Summary

Bronchi and Gastrointestinal Cytology Brush
Traditional 510(k) Premarket Notification
May 31, 2017

Applicant Information

Applicant:	Wilson-Cook Medical, Inc. /Cook Endoscopy 4900 Bethania Station Road Winston-Salem, North Carolina 27105
Contact:	Doris A. Hawks, Global Regulatory Affairs Specialist
Phone:	(336) 744-0157 ext. 396293
Fax:	(336) 201-5994

Device Information

Trade Name:	Bronchi and Gastrointestinal Cytology Brush
Common Name:	Endoscopic Cytology Brush
Classification Name:	Endoscope and Accessories
Regulation Number:	21 CFR 876.1500
Product Code:	FDX
Device Class:	Class II
Review Panel:	Gastroenterology-Urology

Predicate Device

Name:	Wilson-Cook Cytology Brush
510(k) Number:	K896318
Date:	Cleared April 9, 1990

Device Description

The Bronchi and Gastrointestinal Cytology Brush (subject device) is a sterile, single use device compatible with the accessory channel of endoscopes. The device consists of stainless steel coil spring terminating in a nylon brush at the distal end. The coil spring and brush are secured inside an extruded polytetrafluoroethylene sheath. The brush is advanced from and retracted into the sheath.

Intended Use

This device is used to collect cells from the bronchi and/or upper and lower gastrointestinal tracts.

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Comparison to Predicate Device

The Bronchi and Gastrointestinal Cytology Brush has the same intended use, principles of operation, fundamental technologies, and materials of construction as the predicate device. The changes to the subject device involve labeling, incorporating the addition of an Instructions for Use with contraindications, and metric dimensional units. These changes do not raise any new questions of safety or effectiveness.

Performance Data

Performance testing consisting of sterilization, shelf life, biocompatibility, and non-clinical bench testing demonstrate that the Bronchi and Gastrointestinal Cytology Brush meets the performance requirements to fulfill the intended use of the device.