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

April 6, 2017

Wilson-Cook Medical, Inc.
Ashley Howard
Regulatory Affairs Specialist I
4900 Bethania Station Road
Winston Salem, NC 27105

Re: K153763
Trade/Device Name: Howell Biliary Aspiration Needle
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCK
Dated: April 3, 2017
Received: April 4, 2017

Dear Ashley Howard:

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,

Charles Viviano -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)*

K153763

Device Name
Howell Biliary Aspiration Needle

Indications for Use *(Describe)*
This device is intended for aspiration biopsy in the biliary system.

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.

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6. 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:	Ashley Howard, Regulatory Affairs Specialist I
Date:	December 30, 2015
Trade Name:	Howell Biliary Aspiration Needle
Common Name:	Biliary Aspiration Needle
Classification Name:	Gastroenterology-Urology biopsy instrument (21 CFR 876.1075, Product Code FCK)
Legally Marketed Devices:	Wilson-Cook Biliary Aspiration Needle (K895900)
Description of the Device:	The Howell Biliary Aspiration Needle is a sterile, single use device that consists of a luer slip handle with adjustment wheel, outer catheter sheath, needle catheter with needle, stylet and winged hub. The device is compatible with endoscopes with a minimum accessory channel of 2.8 mm. The Howell Biliary Aspiration Needle is 200 cm long. The catheter is comprised of PTFE while the needle is stainless steel and the stylet is nitinol.
Intended Use:	The Howell Biliary Aspiration Needle is used for aspiration biopsy in the biliary system.
Technological Characteristics:	The Howell Biliary Aspiration Needle has the same technological characteristics as the Wilson-Cook Biliary Aspiration Needle (K895900) in terms of general design and function, but has minor differences in terms of handle mechanism and the addition of a stylet.
Performance Data:	Performance testing consisting of non-clinical bench testing demonstrates that the Howell Biliary Aspiration Needle met the performance requirements to fulfill the intended use of the device. The device is substantially equivalent to the cleared predicate device.