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

August 4, 2017

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

Re: K171596
Trade/Device Name: ECHO-3-22: Echotip Ultra and EUSN-1, EUSN-3: Echotip Ultrasound Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: II
Product Code: FCG
Dated: June 2, 2017
Received: June 5, 2017

Dear Tiffanny A. 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. 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,

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)*

K171596

Device Name

ECHO-3-22: Echotip Ultra and EUSN-1, EUSN-3: Echotip Ultrasound Needle

Indications for Use *(Describe)*

This device is used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The target population is adult use only.

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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510(k) Summary

Submission Information

Type:	Traditional 510(k) Premarket Notification
Applicant Name:	Wilson-Cook Medical, Inc./ Cook Endoscopy
Applicant Address:	4900 Bethania Station Road Winston-Salem, North Carolina 27105
Contact:	Tiffanny A. Thomas, Global Regulatory Affairs Specialist
Contact Phone:	336.744.0157
Contact Fax:	336.201.5994
Date:	May 31, 2017

Subject Device

Trade Name:	ECHO-3-22: Echotip Ultra; EUSN-1, EUSN-3: Echotip Ultrasound Needle
Common/Usual Name:	Biopsy Needle
Classification:	Gastroenterology-Urology Biopsy Instrument 21 CFR §876.1075, Class II
Procode:	FCG – Biopsy Needle

Predicate Device

Name:	Endoscopic Ultrasound Needle
510(k) Number:	K934356
Date Cleared:	January 30, 1995

Device Description:

The ECHO-3-22: Echotip Ultra and the EUSN-1, EUSN-3: Echotip Ultrasound Needles are sterile, single use devices. The Ultrasound Needles consist of an adjustable luer slip handle, an outer and an inner catheter with a needle, extension locks (ECHO-3-22) or spacers (EUSN-1, EUSN-3), a stylet, and a syringe with a stopcock. All devices are compatible with ultrasound endoscopes with a minimum accessory channel of 2.8 mm. The catheter is made of polyether ether ketone, PEEK (ECHO-3-22), or polytetrafluoroethylene, PTFE (EUSN-1, EUSN-3), while the needle of all devices is stainless steel, and the stylet is nitinol. The tips of the needles are dimpled for echogenicity.

Intended Use

This device is used to sample targeted submucosal gastrointestinal lesions through the accessory channel of an ultrasound endoscope. The target population is adult use only.

Comparison to Predicate Device:

Design changes were made to the predicate Endoscopic Ultrasound Needle cleared to market via K934356. Changes to the device include: catheter length, material, needle dimple area extension length, gauge size, new handle designs and inclusion of a syringe with a stopcock. The subject Ultrasound Needles are equivalent to the predicate device with respect to intended use, key operating principles, and technological characteristics.

Performance Data:

Performance testing consisting of non-clinical bench testing demonstrates that the Ultrasound Needles meet the performance requirements to fulfill the intended use of the device. 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.

Summary of non-clinical testing:

The following non-clinical testing was conducted to demonstrate the performance of the subject device and confirmed that the subject devices perform as intended.

- Functional Testing
- Shelf Life Testing
- Packaging Validation
- Needle Verification and Validation Testing

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process."

Conclusions:

We believe that the subject device is substantially equivalent to the predicate device in terms of intended use, key operating principles, materials 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 and do not affect safety or effectiveness of the device.