February 21, 2018

Wilson-Cook Medical Inc.
Ashley Howard
Regulatory Affairs Specialist I
4900 Bethania Station Road
Winstom-Salem, North Carolina 27105

Re: K163377
Trade/Device Name: Captura® Bronchoscope Biopsy Forceps
Regulation Number: 21 CFR 874.5680
Regulation Name: Bronchoscope (Fixed and Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 16, 2018
Received: January 22, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K163377

Device Name
Captura® Bronchoscope Biopsy Forceps

Indications for Use *(Describe)*
This device is used in obtaining biopsy samples in the bronchi or lungs. This device is indicated for 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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"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."

Traditional 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. 6174
Contact:	Ashley Howard, Specialist I - Regulatory Affairs
Date:	February 15, 2018
Trade Name:	Captura® Bronchoscope Biopsy Forceps
Common Name:	Bronchoscope Biopsy Forceps
Classification Name:	Bronchoscope (flexible or rigid) and accessories
	21 CFR §874.4680, EOQ, Class II
Predicate Device:	Disposable Bronchoscope Biopsy Forceps,
	K923847, cleared November 18, 1992

Indications for Use

This device is used in obtaining biopsy samples in the bronchi or lungs. This device is indicated for adult use only.

Device Description

The Captura® Disposable Bronchoscope Biopsy Forceps (subject device) represents modifications made to the Disposable Bronchoscope Biopsy Forceps (predicate device) currently cleared to market via 510K K923847 by Wilson-Cook Medical, Inc. The Captura® Disposable Bronchoscope Biopsy Forceps consist of a spool handle, coated coilspring catheter, drive cable, forceps cups and forceps housing.

The bronchoscope biopsy forceps is used by passing the device through a prepositioned endoscope to the targeted location. The forceps cups are attached on one end of the coilspring sheath with the spool handle attached to the opposite end. The handle is actuated by moving the spool forward to open the forceps cups and backward to close. The Captura® Bronchoscope Biopsy Forceps have a surgical rim edge around the circumference of the cups and the cups are fenestrated. The cups are opened and pressed against the biopsy site. When the cups are closed, they are pulled away from the biopsy site, pinching off the top surface, obtaining a tissue biopsy.

Substantial Equivalence

Changes were made to the predicate Disposable Bronchoscope Biopsy Forceps cleared to market via K923847. These changes include: a material formulation change for the forceps components, a catheter material change, elimination of a spiked forceps cup option and updated handle design.

These changes to the subject device were made in an effort to improve the strength of the components, improve passage through the endoscope and to facilitate process improvements for components.

The subject device operates in the same manner as the predicate device after these changes. Design verification and design validation testing demonstrated substantial equivalence of the device.

The modified Captura® Disposable Bronchoscope Biopsy Forceps (subject device) is substantially equivalent to the predicate with respect to the intended use, key operating mechanics and technological characteristics.

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 device performs as intended.

- Shelf Life Testing
    - Functional Testing
- Design Validation/Verification Testing
    - Flex and Fracture Design Verification
    - Force to Biopsy
- Packaging Validation
    - Burst Testing
    - Dye Leak Testing

Summary of Biocompatibility Testing

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

- Cytotoxicity
- Sensitization
- Irritation
- Acute toxicity
- Material-mediated Pyrogenicity

Conclusion

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. The non-clinical data support the substantial equivalence of the subject device and the performance testing, verification and validation testing demonstrate that the subject device should perform as intended when used as instructed in the instructions for use. The non-clinical data demonstrates that the subject device performs comparably to the predicate device that is currently marketed for the same intended use.