March 21, 2018

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

Re: K171973
Trade/Device Name: Captura® Disposable Hot Biopsy Forceps
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KGE
Dated: February 15, 2018
Received: February 16, 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,

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)*

K171973

Device Name
Captura® Disposable Hot Biopsy Forceps

Indications for Use *(Describe)*
The Captura® Disposable Hot Biopsy Forceps is used endoscopically in conjunction with monopolar electrosurgical current to obtain gastrointestinal mucosal tissue biopsies and for removal of sessile polyps. 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.

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Captura® Disposable Hot Biopsy Forceps
510(k) Premarket Notification
June 30, 2017

Applicant Information

Applicant:	Wilson-Cook Medical, Inc. / Cook Endoscopy 4900 Bethania Station Road Winston-Salem, North Carolina 27105
Contact:	Ashley Howard, Specialist I – Regulatory Affairs
Phone:	(336) 744-0157 ext. 6174
Fax:	(336) 201-5994

Device Information

Trade Name:	Captura® Disposable Hot Biopsy Forceps
Common Name:	Forceps, Biopsy, Electric
Classification Name:	Endoscopic Electrosurgical Unit and Accessories
Regulation Number:	21 CFR 876.4300
Product Code:	KGE
Device Class:	Class II
Review Panel:	Gastroenterology-Urology

Predicate Device

Name:	Disposable Hot Biopsy Forceps
510(k) Number:	K923470
Date:	Cleared April 21, 1993

Device Description

The Captura® Disposable Hot Biopsy Forceps is a sterile, single use device compatible with the accessory channel of endoscopes. The device consists of stainless steel forceps cups joined to a spool handle by a Pebax-coated stainless steel coilspring catheter and stainless steel drive cable. The handle's spool actuates the opening and closing of the forceps cups and its brass electrosurgical pin is intended for connection to an electrosurgical generator.

Intended Use

The Captura® Disposable Hot Biopsy Forceps is used endoscopically in conjunction with monopolar electrosurgical current to obtain gastrointestinal mucosal tissue biopsies and for the removal of sessile polyps. This device is indicated for adult use only.

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Comparison to Predicate Device
The Captura® Disposable Hot Biopsy Forceps has the same intended use, principles of operation, and fundamental technologies as the predicate device. Changes to the subject device include dimensions, materials, and added contraindications. These changes do not raise new questions of safety or effectiveness.

Performance Data
Performance testing consisting of sterilization, shelf life, biocompatibility, electrical safety, and non-clinical bench testing demonstrate that the Captura® Disposable Hot Biopsy Forceps meets the performance criteria required to fulfill the intended use of the device.

Summary of Non-Clinical Testing and Electrical Testing
Performance testing consisting of sterilization, shelf life, biocompatibility, electrical safety, and non-clinical bench testing demonstrate that the Captura® Disposable Hot Biopsy Forceps meets the performance criteria required to fulfill the intended use of the device. The following summarizes the non-clinical bench testing conducted:

- Endoscope and Active Cord Compatibility
- Biopsy Obtainment and Removal Testing
- Tensile Testing
- Flexibility Testing
- Post-Aging Functional Testing

Conclusion
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. The information and data contained in this notification supports a determination of substantial equivalence.