July 18, 2019

Wilson-Cook Medical, Inc.
Doris Hawks
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Re: K191048
Trade/Device Name: AcuSnare Polypectomy Snare - Duckbill
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: Class II
Product Code: FDI
Dated: April 18, 2019
Received: April 19, 2019

Dear Doris 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

for
Shanil P. Haugen, Ph.D.
Acting Assistant Division Director
DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191048

Device Name
AcuSnare Polypectomy Snare - Duckbill

Indications for Use *(Describe)*

The AcuSnare Polypectomy Snare – Duckbill (ASDB) device is used endoscopically in the removal and cauterization of sessile polyps and pedunculated polyps from within the gastrointestinal tract.

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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008. Special 510k – Summary

April 18, 2019

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:	AcuSnare Polypectomy Snare - Duckbill
Common Name:	Polypectomy Snare
Classification Name:	Endoscopic electrosurgical unit and accessories
Regulation Number:	21 CFR 876.4300
Product Code:	FDI
Classification:	Class II,
Review Panel**:**	Gastroenterology-Urology

Predicate Device

Name:	AcuSnare Polypectomy Snare
510(k) Number:	K173673
Date:	Cleared August 24, 2018

Device Description

The AcuSnare Polypectomy Snare – Duckbill (ASDB) is a sterile, single use device compatible with the accessory channel of endoscope. This type endoscopic polypectomy device is designed to connect to an electrosurgical unit via an active cord accessory and the drive cable delivers energy through the snare head to cut and/or cauterize tissue as described in the instructions for use. The device consists of a handle, sheath, drive cable and wire loop snare head. The sheath is comprised of

polytetrafluoroethylene (PTFE) and is offered in 7 Fr. (2.3 mm) diameter and 240 cm length models. The snare head is available in the shape of a duckbill configuration and offered in a 15 mm or 25 mm width. The stainless-steel drive cable and snare head pass through the sheath and the three ring (polycarbonate) handle allows the user to extend and retract the snare through the distal tip of the sheath.

Intended Use

The AcuSnare Polypectomy Snare – Duckbill (ASDB) device is used endoscopically in the removal and cauterization of sessile polyps and pedunculated polyps from within the gastrointestinal tract.

Substantial Equivalence

Minor design changes were made to the predicate AcuSnare Polypectomy Snare cleared to market via K173673. These changes include adding a new duckbill shape configuration along with cannula components required to manually form the snare into a duckbill shape. Configuration of the snare does not change the method of operation or the intended use of the device. The subject device is substantially equivalent to the predicate device with respect to the intended use, operating mechanism, materials and technological characteristics

Performance Data

The Risk Analysis was completed to access the impact of modifications made to the cleared device using the Design Failure Modes, Effects and Criticality Analysis (DFMECA) method. Design verification and/or validation testing was performed as a result of this risk analysis assessment. 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 and demonstrate that the AcuSnare Polypectomy Snare – Duckbill (ASDB) meets the performance requirements to fulfill the intended use of the device.

Conclusion

We believe risks associated with the modifications to the subject device have been adequately addressed through our Design Control Processes. We believe that the subject device is substantially equivalent to the predicate device in terms of intended use and performance characteristics (key operating principles, materials and technological characteristics).