August 24, 2018

Wilson-Cook Medical, Inc
Theresa de Prat
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Re: K173673
Trade/Device Name: AcuSnare Polypectomy Snare
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: FDI
Dated: July 10, 2018
Received: July 11, 2018

Dear Theresa de Prat:

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,

Glenn B. Bell -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)*
K173673

Device Name
AcuSnare Polypectomy Snare

Indications for Use *(Describe)*
This 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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: Theresa de Prat, Regulatory Affairs Specialist II
Date: November 30, 2017

Device Identification

Trade Name: AcuSnare Polypectomy Snare
Common Name: Polypectomy Snare
Regulation Number: 876.4300
Classification Name: Endoscopic electrosurgical unit and accessories.
Product Code: FDI
Regulatory Class: Class II
Classification Panel: Gastroenterology and urology
Classification Name: snare, flexible
Predicate Devices: Rotatable Polypectomy Snare (POS-1) K851958; cleared July 25, 1985
Single Use Electrosurgical Snare (SD-400) K172734; cleared December 7, 2017

Intended Use:
This subject device is used endoscopically in the removal and cauterization of sessile polyps and pedunculated polyps from within the gastrointestinal tract.

Device Description:
The subject device consists of a handle section, a sheath section and a snare head section. The snare head section is inserted into the sheath section and is extended and retracted by operating the three-ring handle section.

The sheath section and the snare head section are inserted in the gastrointestinal tract through an endoscope. The snare head is extended from the sheath to resect target polyps. This resection is performed with high-frequency current.

Substantial Equivalence:
Minor changes were made to the first predicate device Rotatable Polypectomy Snare (K851958) and second predicate Single Use Electrosurgical Snares SD-400(K172734). These changes include updating the intended use to the removal and cauterization of sessile polyps and pedunculated polyps from within the gastrointestinal tract, adding additional stainless-steel types to snare head materials of construction,

and a new snare head shape configuration ("needle-tip"), and a different thermoplastic for the handle of the subject device.

Comparison table of subject device and predicate device:

	(Subject Device) AcuSnare Polypectomy Snare	(1st Predicate K851958) Wilson-Cook Medical Rotatable Polypectomy Snare	(2nd Predicate K172734) Single Use Electrosurgical Snare SD-400.
Intended Use	This device is used endoscopically in the removal and cauterization of sessile polyps and pedunculated polyps from within the gastrointestinal tract.	To snare and remove polyps from the colon.	These instruments have been designed to be used with an Olympus endoscope for the removal and/or cauterization of diminutive polyps, sessile polyps, pedunculated polyps and tissue from within the GI tract.
Classification Name:	Snare Flexible	Same	Same
Common/Usual Name:	Polypectomy Snare	Polypectomy Snare	Snares
Trade/or Proprietary Name	AcuSnare Polypectomy Snare	Rotatable Polypectomy Snare (POS-1)	Single Use Electrosurgical Snares (SD-400)
Class:	Class II	Same	Same
Product Code	FDI	FGX	FDI FGX
Configuration:	Oval, hexagon, needle-tip	Oval, crescent and hexagon	Hexagon
Snare Material:	#304 /#302 / #303 Stainless Steel	#304 Stainless Steel	Stainless Steel
Sheath Material:	Teflon (PTFE)	Teflon (PTFE)	Fluorocarbon polymer
Handle Material:	PC	Unknown	ABS
Length:	240 cm	240 cm	230 cm
Catheter FR Size:	7 FR	7 FR	Unknown
Sterile/non-sterile:	Sterile	Sterile	Sterile
Sterilization method:	Ethylene Oxide	Same	Same
Reusable/Single Use:	Single Use	Reusable	Single Use
Used with Electrosurgical Unit:	Yes	Yes	Yes

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
- Package Integrity Testing
- Tensile test snare to catheter

- Tensile test catheter to handle
- Snare head to drive cable joint
- Snare wire to cannula joint
- Handle/Cannula/Drive Cable joint
- Pin to Handle Joint
- IEC 60601-1: 2006 + A12: 2014- Medical electrical equipment – Part 1: General requirements for basic safety and essential performance of High Frequency Surgical Equipment and High frequency Surgical Accessories
- IEC 60601-2-2: 2017 - Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories
- IEC 60601-2-18: 2009 - Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

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" and per ISO 10993-1:2009, *Biological evaluation of medical devices-Evaluation and testing within risk management process.*

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. 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.