January 25, 2019

Wilson-Cook Medical, Inc.
Theresa de Prat
Regulatory Affairs Specialist II
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K182895
Trade/Device Name: Wilson-Cook Achalasia Balloon
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: PID
Dated: October 22, 2018
Received: October 23, 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,

Daniel G. Walter Jr -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182895

Device Name
Wilson-Cook Achalasia Balloon

Indications for Use *(Describe)*
The device is used to dilate the lower esophageal sphincter in patients with Achalasia. 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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Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Wilson-Cook Medical, Inc. / Cook Endoscopy
Contact:	Theresa de Prat
Applicant Address:	Wilson-Cook Medical, Inc. / Cook Endoscopy 4900 Bethania Station Road Winston-Salem, North Carolina 27105

Contact Phone Number: (336) 744-0157
Contact Fax Number: (336) 201-5994

Device Information

Trade Name:	Wilson-Cook Achalasia Balloon
Common Name:	Dilation Balloon
Regulation Description:	Gastrointestinal tube and accessories
Regulation Number:	21 CFR 876.5980
Product Code:	PID
Device Class:	Class II
Review Panel:	Gastroenterology-Urology

Predicate Device

Name:	Rigiflex II Single Use Achalasia Balloon Dilator
510(k) Number:	K050232
Date:	03/11/2005

Intended Use

The device is used to dilate the lower esophageal sphincter in patients with Achalasia. This device is indicated for adult use only**.**

Device Description

The subject dilation balloon consists of an PET balloon attached to a 75 cm that is secured to a white Pebax Y junction with two extension lines leading ending with a wire guide hub and an inflation hub. The catheter has four black ink markers on the catheter.

The dilation balloon is composed of PET, with a patient contacting length of 8 cm which can be inflated to a single size of 30 mm or 35 mm in diameter. The balloon has a 1.16” long tip made of white Neuthane. Three tantalum radiopaque bands are placed underneath the balloon to assist in fluoroscopic visualization of the balloon.

Model	Catheter		Balloon			
Reorder Part Number	Catheter Diameter (FR)	Catheter Length (cm)	Inflated Balloon Diameter	Balloon Length (cm)	Recommended Graduated Pressure (PSI)	Recommended Graduated Pressure (atm)
WCAB-30	14.5	75	30mm (90FR)	8	45	3.0
WCAB-35	14.5	75	35mm (105FR)	8	40	2.7

Comparison to Predicate Device
The subject device, the Wilson-Cook Achalasia Balloon, is substantially equivalent to the Rigiflex II Single-Use Achalasia Balloon Dilator (K050232) with respect to intended use, operating mechanism, technological characteristics.
Minor changes exist from the predicate Rigiflex II Single-Use Achalasia Balloon Dilator to the Wilson Cook Achalasia Balloon (subject device).
The subject device has a more specific intended use, different materials of construction, a shorter balloon patient contacting length, dimensional differences in catheter dimeter and length and provided non-sterile. The subject device has a maximum balloon inflation pressure of 3.0 atm while the predicate has a maximum inflation pressure of 1.36 atm. These minor differences do not raise new questions of safety or effectiveness.

Summary of Non-Clinical Testing
The following performance testing was conducted to demonstrate performance of the subject device and confirmed that the subject device performs as intended.

- Balloon Diameter and Length
- Balloon Pressure Verification
- Distensibility
- Tensile Testing of Joint Components
- Dimensional Verification (catheter and balloon)
- Functional Testing
- Shelf Life 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" and per ISO 10993-1:2009, *Biological evaluation of medical devices- Evaluation and testing within risk management process.*

Conclusion
Results from design validation and/or verification testing provide reasonable assurance that the modifications do not raise new questions of safety or effectiveness. Therefore, we believe the subject device to be substantially equivalent to the predicate.