October 12, 2017

Wilson-Cook Medical, Inc.
Sierra Lowe
Regulatory Affairs Specialist - 1
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K171548
Trade/Device Name: Cotton® Graduated Dilation Catheter, Fusion® Biliary Dilation Catheter, Soehendra® Biliary Dilation Catheter, Geenen® Graduated Dilation Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: August 18, 2017
Received: August 21, 2017

Dear Sierra Lowe:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -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)*
K171548

Device Name
Cotton® Graduated Dilation Catheter, Fusion® Biliary Dilation Catheter, Soehendra® Biliary Dilation Catheter, Geenen® Graduated Dilation Catheter

Indications for Use *(Describe)*

The Cotton® Graduated Dilation Catheter, Fusion® Biliary Dilation Catheter, Soehendra® Biliary Dilation Catheters are used to dilate biliary strictures. These devices are indicated for adult use only.

The Geenen® Graduated Dilation Catheter is used to dilate stenotic minor papilla. These devices are 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.

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."

COOK ENDOSCOPY
4900 BETHANIA STATION ROAD
WINSTON-SALEM, NC 27105 U.S.A.
PHONE: 336.744.0157 TOLL FREE: 800.245.4707
WWW.COOKMEDICAL.COM

510(k) Summary

Name:	Wilson-Cook Medical, Inc. /Cook Endoscopy
Address:	4900 Bethania Station Road
	Winston-Salem, North Carolina 27105
Phone:	(336) 744-0157 (x396506)
Fax:	(336) 201-5994
Contact:	Sierra Lowe, Regulatory Affairs Specialist I
Date:	October 13, 2017
Trade Names:	Cotton® Graduated Dilation Catheter (CGDC)
	Fusion® Biliary Dilation Catheter (FS-BDC)
	Soehendra® Biliary Dilation Catheter (SBDC)
	Geenen® Graduated Dilation Catheter (GGDC)
Common Name:	Dilation Catheter
Classification Name:	Biliary Catheter and Accessories 21 CFR §876.5010; FGE Class II
Predicate Devices:	Soehendra® Biliary Dilation Catheter, K851960, cleared April 18, 1985
	Vennes® Pancreatic Dilation Set, K851956, cleared June 13, 1985

Intended Uses:

The Cotton® Graduated Dilation Catheter, Fusion® Biliary Dilation Catheter, Soehendra® Biliary Dilation Catheters are used to dilate biliary strictures. These devices are indicated for adult use only.

The Geenen® Graduated Dilation Catheter is used to dilate stenotic minor papilla. These devices are indicated for adult use only.

Description of the Devices:

Biliary Dilation Catheters

The subject devices consist of a catheter with a luer lock hub with a connecting cap fitting. The Fusion® Biliary Dilation Catheter is constructed with a double lumen, radiopaque catheter with a stylet wire that is removed prior to contrast or fluid injection. The subject devices are used by passing the device through an endoscope, over a pre-positioned wire guide. The device is then advanced under fluoroscopic monitoring; during advancement, the pre-positioned wire guide will exit the proximal (non-patient contacting) end of the catheter through the connecting cap and luer lock hub. The Fusion® Biliary Dilation Catheter includes an additional option which allows the wire guide to exit at the distal end of the device (patient contacting). The dilation catheter is advanced to the appropriate position where dilation of the stricture is completed.

Dilation Catheter

The subject device consists of a catheter with a radiopaque marker band and a luer lock hub with a connecting cap fitting. The subject device is used by passing the device through an endoscope, over a pre-positioned wire guide. The device is then advanced under fluoroscopic monitoring; during advancement, the pre-positioned wire guide will exit the proximal (non-patient contacting) end of the catheter through the connecting cap and luer lock adapter. The dilation catheter is advanced to the appropriate position where dilation of the stricture is performed.

Substantial Equivalence:

Biliary Dilation Catheter

Minor changes were made to the predicate dilation catheters cleared to market via K851960. Changes to the subject devices include: additional catheter lengths and diameters, additional tapered tip lengths and diameters, and the addition of tantalum radiopaque marker bands. For the Fusion® Biliary Dilation Catheter (FS-BDC), there was a change to the catheter material and the addition of a stylet wire.

Dilation Catheter

Minor changes have been made to the predicate dilation catheter cleared to market via (K851956). Changes to the subject device include: additional catheter lengths and diameters, additional tapered tip lengths and diameters, addition of tantalum radiopaque marker bands, exclusion of the wire guide that was previously supplied along with the device, and updated wire guide compatibility.

Performance Data:

Performance testing consisting of non-clinical bench testing demonstrates that the subject devices met the performance requirements to fulfill their intended uses. The results of this testing provides reasonable assurance that the subject devices will function as intended. The subject devices do not raise new questions of safety or effectiveness as compared to their respective predicate devices.

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
- Packaging Validation
- Non-clinical, bench testing of the subject devices – methods included: visual inspection, pre-position guidewire verification, endoscope channel compatibility, dilatation simulation, simulated removal, and removal force and tensile strength tests

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."

Conclusion:

We believe that the subject devices are substantially equivalent to the predicate devices in terms of intended use, key operating principles, materials and technological characteristics. We consider the risks associated with the modifications to the subject devices to have been adequately addressed through our Design Control Processes and do not affect safety or effectiveness of the devices.