March 20, 2018

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

Re: K171989
Trade/Device Name: Classic ERCP Catheter (ERCP),
Huibregtse-Katon® ERCP Catheter (ERCP),
Huibregtse-Katon® Angled ERCP Catheter (ERCP),
Glo-Tip® ERCP Catheter (GT),
Glo-Tip® ERCP Catheter with Radiopaque Bands (GT),
Fusion® ERCP Catheter with DomeTip® (FS-GT)
Fusion® OMNI ERCP Catheter with DomeTip®(FS-GT),
Glo-Tip II® Double Lumen ERCP Catheter (GT)
Glo-Tip II® Double Lumen ERCP Catheter with Radiopaque Bands (GT),
Haber RAMP™ Catheter (HRC),
Soehendra Universal Catheter (SUC)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: ODD
Dated: February 8, 2018
Received: February 9, 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)*

K171989

Device Name
ERCP Catheters (ERCP, GT, FS-GT, HRC and SUC)

Indications for Use *(Describe)*
This device is used for endoscopic cannulation of the ductal system. 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.

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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: 765.436.7537 ext. 6174
Fax: 336.201.5994
Contact: Ashley Howard, Specialist I – Regulatory Affairs

Date: March 20, 2018

Subject Device Trade Names:
Classic ERCP Catheter (ERCP)
Huibregtse-Katon® ERCP Catheter (ERCP)
Huibregtse-Katon® Angled ERCP Catheter (ERCP)
Glo-Tip® ERCP Catheter (GT)
Glo-Tip® ERCP Catheter with Radiopaque Bands (GT)
Fusion® ERCP Catheter with DomeTip® (FS-GT)
Fusion® OMNI ERCP Catheter with DomeTip® (FS-GT)
Glo-Tip II® Double Lumen ERCP Catheter (GT)
Glo-Tip II® Double Lumen ERCP Catheter with Radiopaque Bands (GT)
Haber RAMP™ Catheter (HRC)
Soehendra® Universal Catheter (SUC)

Common Name: ERCP Catheters
Classification Name: Endoscopic Retrograde Cholangiography (ERCP) Cannula; ODD; Class II

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Predicate Device: Endoscopic Retrograde Cholangiography Catheter (E.R.C.P); K851964, cleared June 13, 1985

Intended Use

This device is used for endoscopic cannulation of the ductal system. This device is indicated for adult use only.

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Device Description:

The subject devices consist of a catheter with a T-fitting, a Y-body connector, a hub, or a female luer lock on the proximal handle and 3 MM markings at the distal radiopaque tip.

The device distal tip configurations include stainless steel metal, tapered, dome and/or angled tips. ERCP catheters are available in single, double, or triple lumen configurations. All devices have an injection port/wire guide port. Some catheters include a stylet wire to facilitate advancement of the catheter, which is removed prior to wire guide insertion or contrast injection. ERCP catheters are used by passing the device through an endoscope. The injection port/wire guide port is then used to allow fluoroscopic visualization by injecting contrast and/or wire guide access to the desired duct.

Substantial Equivalence:

Minor changes were made to the predicate catheter cleared to market via K851964. Changes to the subject devices include: labeling to incorporate the addition of Instructions for Use with contraindications, catheter length, diameter, stylet wire material and size, type and number of radiopaque and ink markings, handle design, and number of lumens. The device is also now disposable, single use.

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 provide 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.

- Functional Age Testing
- Design Validation of Fluoroscopic Visibility

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- Force to Remove ERCP w/ Metal Tips from Ductal System
- Radiopaque Band Detachment
- Verification Testing Force to Peel Through
- Tensile Strength of Metal Tip to Catheter Joint
- Package Integrity
- EO Residual Testing

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 ERCP catheters (ERCP, GT, FS-GT, HRC and SUC) 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.