April 17, 2018

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

Re: K172288
Trade/Device Name: Fusion® OMNI™ Sphincterotome
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KNS
Dated: March 6, 2018
Received: March 7, 2018

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.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172288

Device Name

Fusion® OMNI™ Sphincterotome

Indications for Use *(Describe)*

This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP.

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.

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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

Fusion® OMNI Sphincterotome
Traditional 510(k) Premarket Notification

March 6, 2018

Applicant Information

Applicant:	Wilson-Cook Medical, Inc. /Cook Endoscopy 4900 Bethania Station Road Winston-Salem, North Carolina 27105
Contact:	Sierra Lowe, Specialist I – Regulatory Affairs
Phone:	(336) 744-0157 ext. 396506
Fax:	(336) 201-5994

Device Information

Trade Name:	Fusion® OMNI Sphincterotome
Common Names:	Papillotome, sphincterotome
Classification Name:	Endoscopic electrosurgical unit and accessories
Regulation Number:	21 CFR 876.4300
Product Code:	KNS
Device Class:	Class II
Review Panel:	Gastroenterology-Urology

Predicate Device

Name:	Wilson-Cook OMNI™ Sphincterotome
510(k) Number:	K052051
Date:	Cleared June 18, 1990

Intended Use

This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP.

Device Description

The Fusion® OMNI Sphincterotome (subject device) is a sterile, single use device compatible with the accessory channel of endoscope. The device consists of a long, thin plastic tube (cannula) with a wire running the length of its interior. A small portion of that wire is exposed at its distal end. The roof of the papilla is opened by passing high- frequency current through the wire, exposing the biliary or pancreatic orifices for selective cannulation.

Substantial Equivalence

Minor changes have been made to the predicate sphincterotomes cleared to market via K052051. The most notable changes to the subject devices include: Slightly different catheter diameters and compatible wire guide diameters to accommodate a range of endoscope channels and/or smaller papilla, inclusion of a wire guide port at the distal end (patient contacting end) of the device in order to facilitate an additional option to perform a device exchange, slightly decreased maximum rated input voltage in order to be representative of the results of the electrical testing conducted on the subject devices.

The subject device and predicate device have the same intended use and different technological characteristics. None of the differences in technological characteristics raise different questions of safety and effectiveness. Furthermore, performance data from acceptable scientific testing methods provide evidence that the subject device is substantially equivalent to the predicate device.

Performance Data

Performance testing consisting of sterilization, shelf life, biocompatibility, and non-clinical bench testing demonstrate that the Fusion® OMNI Sphincterotome meets the performance requirements to fulfill the intended use of the device.

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: sterile barrier inspection, functional testing, drive wire to handle joint strength, brass insert to handle joint strength, fluoroscopic visibility, active cord pin detachment.
- The electromagnetic compatibility and electrical safety of the subject devices were assessed in accordance with the following standards: IEC 60601-1: 2005 + A1: 2012 (3.1

edition)- Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, IEC 60601-2-2: 2017 (6.0 edition) - 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, and IEC 60601-2-18: 2009 (3.0 edition) - Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

- Biocompatibility testing was conducted in accordance with ISO 10993-1:2009 and FDA Guidance: Use of International Standard ISO 10993-1:2009 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".