December 29, 2017

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

Re: K171573
Trade/Device Name: Fusion® Cytology Brush, CytoMax II® Double Lumen Cytology Brush
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDX
Dated: November 29, 2017
Received: December 4, 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.

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,

Charles Viviano -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)*

K171573

Device Name
Fusion® Cytology Brush
CytoMax II® Double Lumen Cytology Brush

Indications for Use *(Describe)*
The Fusion® Cytology Brush and CytoMax II® Double Lumen Cytology Brush are used for collection of cells in the biliary system.

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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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:	May 26, 2017
Trade Names:	Fusion® Cytology Brush CytoMax II® Double Lumen Cytology Brush
Common Name:	Endoscopic Cytology Brush
Classification Name:	Endoscope and accessories 21 CFR §876.1500, FDX, Class II
Predicate Device:	Wilson-Cook Double Lumen Biliary Cytology Brush, K040324, cleared May 20, 2004.
Intended Use:	The Fusion® Cytology Brush and CytoMax II® Double Lumen Cytology Brush are used for collection of cells in the biliary system.

Device Description:

The Fusion® Cytology Brush and CytoMax II® Double Lumen Cytology Brush (subject devices) represent modifications made to the Wilson-Cook Double Lumen Biliary Cytology Brush (predicate device) currently cleared to market via 510K K040324 by Wilson-Cook Medical, Inc.

The Fusion® Cytology Brush and CytoMax II® Double Lumen Cytology Brushes consist of a double lumen catheter with ink markings, a cytology brush assembly with either a coil spring or bullet tip, a pin vise handle, wire guide hub, and a detachable connecting tube, which can be used for flushing of the wire guide hub. The endoscopic cytology brush is used by passing the device through an endoscope, over a

prepositioned wire guide to the target location. The endoscopic cytology brush assembly is located at the distal (patient contacting) end with the pin vise handle located at the proximal (non-patient contacting) end. The handle is actuated by pushing the pin vise handle forward to extend the cytology brush and then pulling backward to retract the brush.

Substantial Equivalence:

Changes have been made to the currently cleared Double Lumen Biliary Cytology Brushes (K040324). These changes include: catheter length labeling to reflect working length, additional catheter diameters, brush tip diameters and lengths, removal of a 6cm ink marking, removal of radiopaque markers, modified wire guide access port, removal of wire guide port with extension, updated wire guide compatibility, and modified catheter materials. 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.

- Shelf Life Testing
- Packaging Validation

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 device 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.