February 8, 2019

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

Re: K181317
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: Class II
Product Code: FDX
Dated: January 10, 2019
Received: January 11, 2019

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,

Angel A. Soler-garcia -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)*
K181317

Device Name
Fusion Cytology Brush
CytoMax II Double Lumen Cytology Brush

Indications for Use *(Describe)*
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.

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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"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."

009. 510k Summary

510(k) Summary

Name: Wilson-Cook Medical, Inc. /Cook Endoscopy

Address: 4900 Bethania Station Road
Winston-Salem, North Carolina 27105

Phone: (336) 744-0157

Fax: (336) 201-5994

Contact: Theresa de Prat, Regulatory Affairs Specialist II

Date: May 18, 2018

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 Devices: Wilson-Cook CytoMax II® Double Lumen Cytology Brush
Wilson-Cook Fusion® Cytology Brushes cleared on December 29, 2017 under K171573.

Intended Use: 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 and Fusion® Cytology Brush (predicate devices) cleared to market via 510(k) K171573 by Wilson-Cook Medical, Inc.

The Fusion® Cytology Brush and CytoMax II® Double Lumen Cytology Brushes consist of a nylon brush on a stainless-steel drive wire with a stainless-steel tip, a double lumen catheter with ink markings, radiopaque markers, wire guide access via a wire guide hub or an IDE port, a

detachable extension line with a leur lock for optional flushing of the wire guide hub and a pin-vise handle.

The Fusion® Cytology Brush and CytoMax II® Double Lumen Cytology Brushes are used by passing the device through an endoscope over a prepositioned wire guide to a target location. The cytology brush is located at the distal end (patient contacting) of the device with the pin vise handle located at the proximal end (non-patient contacting). 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:

Modifications were made to the currently cleared Wilson-Cook CytoMax II® Double Lumen Cytology Brush and Wilson-Cook Fusion® Cytology Brushes (K171573). These changes include: catheter diameter and length, wire guide size compatibility changes including wire guide access port and recommended endoscope channel sizes.

Performance Data:

Performance testing consisting of non-clinical bench testing that demonstrates the subject devices met the performance requirements to fulfill their intended use. This testing 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 the predicate devices.

Summary of non-clinical testing:

The following non-clinical testing was conducted to demonstrate the performance of the subject devices and confirms that the subject devices perform as intended.

- Shelf Life Testing
- Packaging Validation
- Tensile Strength Testing
- Tensile Strength of Handle
- Force to Retract Brush

- Wire Guide Compatibility

Biocompatibility testing was performed in accordance with 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 ISO 10993-1:2009 *Biological evaluation of medical device: Evaluation and testing within a risk management process* for surface devices with limited mucosal membrane contact.

Conclusion:

We believe that the subject devices are substantially equivalent to the predicate devices with respect to intended use, key operating principles, materials of construction, 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 the safety or effectiveness of the devices.