August 3, 2018

Hologic, Inc.
Christine M. Cameron
Manager, Regulatory Affairs
250 Campus Drive
Marlborough, MA 01752

Re: K180825
Trade/Device Name: Fluent Fluid Management System
Regulation Number: 21 CFR§ 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: II
Product Code: HIG, HIH
Dated: July 3, 2018
Received: July 5, 2018

Dear Christine M. Cameron:

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,

Michael T. Bailey -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180825

Device Name
Fluent Fluid Management System

Indications for Use *(Describe)*
The Fluent Fluid Management System is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus while providing drive, control and suction for hysteroscopic morcellators.

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.

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510(k) SUMMARY

Date: July 31. 2018

5.1. **510(k) Submitter:**

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
Telephone: 508.263.8654
Establishment Registration Number: 1222780

Contact: Christine Cameron, Regulatory Affairs Manager
Email: Christine.Cameron@hologic.com
Phone: 508-263-8654

5.2. **Device:**

Trade Name: Fluent Fluid Management System
Common/Usual Name: Hysteroscopic Insufflator
Regulation Number: 21.CFR.Reg 884.1700
Regulation Name: Hysteroscopic insufflator
Product Code: HIG (insufflator, hysteroscopic), HIH (hysteroscope (and accessories))
Device Class: Class II

5.3. **Predicate Devices:**

Predicate 1
Tradename: Aquilex Fluid Control System H112
Submitter / 510(k) Holder: W.O.M. World of Medicine AG
510(k) #'s: K112642

Predicate 2
Tradename: MyoSure Tissue Removal Device System and MyoSure Tissue Removal Devices
Submitter / 510(k) Holder: Hologic, Inc.
510(k) #'s: K172566

The predicate devices have not been subject to a design related recall.

5.4. **Device Description:**

The Fluent Fluid Management System is a hysteroscopic fluid management system and drive console for hysteroscopic morcellators.

The Fluent Fluid Management System consists of a console and single-use procedure kit. The single use procedure kit consists of a sterile Inflow Tube Set (In-FloPak) and Outflow Tube Set (Out-FloPak) with a nonsterile Waste Bag. The two FloPaks and Waste Bag connect to the Console for performing hysteroscopic procedures. The console includes motors that control inflow and outflow of fluid for hysteroscopic insufflation, as well as a pressure sensor monitoring system and graphical user interface touchscreen.

In addition, the console includes a connection for MyoSure Tissue Removal Devices and a pneumatic foot pedal to perform tissue removal procedures. The Fluent Fluid Management System is compatible with currently marketed MyoSure Tissue Removal Devices.

The primary functions of the subject device are fluid distension, fluid deficit tracking, and morcellator drive control. The subject device includes a deficit alert feature as well as an overpressure protection mechanism.

5.5. **Indications for Use:**

The Fluent Fluid Management System is intended to provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus while providing drive, control and suction for hysteroscopic morcellators.

The subject device has the same general intended use as the primary and secondary predicate devices, respectively: (1) to provide liquid distension of the uterus while monitoring irrigation fluid and (2) to provide drive control for morcellators during hysteroscopic procedures. The subject device indications include reference to both the fluid management function of the primary predicate and the “drive, control, and suction for hysteroscopic morcellators” function of the secondary predicate to reflect the combination of these two device functions into the subject device. These features do not interfere with each other and do not change the overall intended use relative to the predicate devices.

5.6. **Comparison of Characteristics:**

The method of use, mechanism of action, mode of operation and functional performance of the Fluent Fluid Management System are substantially equivalent to the Aquilex Fluid Control System H112 (K112642) for fluid management utilized for uterine distention as well as the MyoSure Tissue Removal Device System, specifically the console for providing drive, control and suction for the MyoSure Tissue Removal Devices for tissue removal (K172566).

Table 5-1: Device Comparison of Technological Characteristics				
Device and Predicate Devices	**Aquilex Fluid Control System** **K112642** **Predicate 1**	**MyoSure Tissue Removal System** **K172566** **Predicate 2**	**Fluent Fluid Management System** **Subject Device**	**Comparison to Predicates**
General Device Characteristics				
Method of Use	Uterine distention	Drive, control, and suction for hysteroscopic morcellators and hysteroscopic resection and removal of tissue via tissue removal devices	Uterine distension (fluid management) and drive, control, and suction for hysteroscopic morcellators	Similar
Mechanism of Action	Fluid flow with a single roller peristaltic pump for irrigation and a diaphragm pump for vacuum.	The console provides mechanical control, drive, and suction for the hysteroscopic morcellator.	Fluid flow with a single peristaltic pump for irrigation and single peristaltic pump for vacuum.	Similar

Mode of Operation	Provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus	Vacuum is used to pull tissue into the side- facing cutting window where it is cut and aspirated through the cutter and deposited into a collection canister.	Provide liquid distension of the uterus during diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus. Vacuum is created to pull tissue into the side-facing cutting window where it is cut and aspirated through the cutter and deposited into a collection canister.	Similar
Fluid Management System				
Pressure Control Range	40-150mmHg	N/A	40-120mmHg	Different
Maximum Intrauterine Pressure	150mmHg	N/A	120mmHg	Different
Flow rate (maximum)	800mL/min	N/A	650mL/min	Different
Overpressure Protection	Yes	N/A	Yes	Same
Fluid Deficit Tracking	Yes	N/A	Yes	Same
Drive Control Console for Hysteroscopic Morcellators				
Morcellator drive Rotation Speed	N/A	8075±1000 RPM	8075±1000 RPM	Same

The descriptive characteristics of the Fluent Fluid Management System and the predicate devices are shown in the table above. K112642 is the primary predicate used to compare the technological characteristics of the fluid management function (hysteroscopic insufflator) of the subject device, while K172566 is used only to compare the morcellator drive-control console function of the subject device. The combination of these features does not change the intended use or risk profile relative to the independent predicate devices.

The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.

5.7. **Performance Testing:**

Sterility and Shelf Life

For the sterile Inflow/Outflow tubing, EtO sterilization validation per ISO 11135:2014 and EtO and ECH residual testing in accordance with ISO 10993-7:2008 were conducted. In addition, package integrity testing per ASTM F1980-16 and transport validation and accelerated aging testing with functional testing were performed for the sterile components in order to confirm the three-year shelf life.

Biocompatibility:

- Cytotoxicity - ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- Sensitization - ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Irritation - ISO10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization
- Acute System Toxicity – ISO 10993-11:2006 – Part 11: Tests for systemic toxicity

Software

The Fluent Fluid Management System successfully performed system design control verification and validation testing, which included software documentation for a Major Level of Concern in accordance with FDA's *Guidance for the Content of premarket Submissions for Software Contained in Medical Device*s (issued on May 11, 2005).

Electrical Safety and EMC:

- IEC 60601-1:2005 + A1:2012, C1:2009 + A2:2010 Medical Electrical Equipment - Part 1 General requirements for safety and essential performance.
- IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010 (Third Edition) + A1:2013 Medical electrical equipment - Part 1-6: Particular requirements for the basic safety and essential performance: Usability

Performance Testing

Non-clinical performance testing was conducted to verify the functional performance of the subject device. The performance testing included the following:

- Design verification (mechanical testing) of the inflow/outflow tubing sets
- Fluid management validation testing to assess inflow rate, outflow rate, and TRD suction
- Intrauterine pressure control testing
- System performance testing
- System cutting performance for the drive control system

5.8. **Conclusion:**

The performance data demonstrate that the Fluent Fluid Management System is substantially equivalent to the predicate devices.