July 25, 2024

Hologic, Inc.
Meghan Wakeford
Principal Regulatory Affairs Specialist
250 Campus Drive
Marlborough, Massachusetts 01752

Re: K240886
Trade/Device Name: Fluent Pro Fluid Management System (FLT-200);
Fluent Pro Fluid Management System Disposable Procedure Kit (6-pack) (FLT-212);
Fluent Pro Fluid Management System Disposable Procedure Kit (1-pack) (FLT-212S);
Fluent Pro Fluid Management System Tissue Trap Multipack (10-pack) (FLT-210);
Fluent Pro Fluid Management System Waste Bag Multipack (5-pack) (FLT-205)
Regulation Number: 21 CFR 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: II
Product Code: HIG, HIH
Received: June 27, 2024

Dear Meghan Wakeford:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240886

Device Name
Fluent Pro Fluid Management System

Indications for Use *(Describe)*
The Fluent Pro 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 liquid 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.

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Traditional 510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92

Date Prepared: March 29, 2024

Manufacturer:
Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA

Establishment Registration #: 1222780

Contact Person:
Meghan Wakeford
Principal Regulatory Affairs Specialist
P: 508.263.6172

Identification of the Device:

Proprietary/Trade Name:	Fluent® Pro Fluid Management System
Classification Name:	Hysteroscopic Insufflator
Regulatory Number:	21 CFR 884.1700
Product Codes:	HIG (Hysteroscopic Insufflator), HIH (Hysteroscope and accessories)
Device Class:	Class II
Review Panel:	Obstetrics/Gynecology

Identification of the Legally Marketed Predicate Device:

Trade Name:	Fluent® Fluid Management System
Classification Name:	Hysteroscopic Insufflator
Regulatory Number:	21 CFR 884.1700
Product Codes:	HIG (Hysteroscopic Insufflator), HIH (Hysteroscope and accessories)
Device Class:	Class II
Review Panel:	Obstetrics/Gynecology
Submitter/510(k) Holder:	Hologic, Inc.
Clearance:	K180825 (August 3, 2018)

The legally marketed predicate device, the Fluent Fluid Management System (K180825) has not been subject to design-related recalls.

Device Description:
The Fluent Pro Fluid Management System is a hysteroscopic fluid management system and drive console for hysteroscopic morcellators. The Fluent Pro Fluid Management System consists of a console and single-use procedure kit. The single-use procedure kit consists of sterile inflow (In-FloPak) and outflow (Out-FloPak) tube sets, and a non-sterile waste bag. The FloPaks and waste bag connect for use in hysteroscopic procedures. The console includes motors that control fluid inflow and outflow for hysteroscopic insufflation, as well as a pressure sensor monitoring system and graphical user interface.

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

Indications for Use:
The Fluent Pro 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 liquid flowing into and out of the uterus while providing drive, control and suction for hysteroscopic morcellators.

Standards:
- ISO 14971:2019 – Medical Devices – Application of Risk Management to Medical Devices
- ISO 10993-1:2018 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
- IEC 60601-1:2005 + A1:2012 + A2:2020 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 + A1:2020 – Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- IEC 62304:2006 + A1:2015 – Medical Device Software – Software Life Cycle Processes
- IEC 62366-1:2015 + A1:2020 – Medical Devices – Part 1: Application of Usability Engineering to Medical Devices

FDA Guidance Documents:
- "Hysteroscopic and Laparoscopic Insufflators: Submission Guidance for a 510(k)," issued July 31, 1995
- "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process'" issued September 8, 2023
- "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile," issued January 8, 2024
- "Content of Premarket Submissions for Device Software Functions," issued June 14, 2023
- "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions," issued September 27, 2023.
- "Electromagnetic Compatibility (EMC) of Medical Devices," issued June 6, 2022
- "Applying Human Factors and Usability Engineering to Medical Devices," issued February 3, 2016

Comparison with Predicate Device:
The Hologic Fluent Pro Fluid Management System has the same intended use, method of operation, and key functional elements as the predicate device, the Hologic Fluent Fluid Management System (K180825). The proposed device presents similar technological characteristics as the predicate device in order to provide fluid distention of the uterus during diagnostic and operative hysteroscopy procedures and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus, while providing drive, control, and suction for the MyoSure tissue removal devices.

Substantial Equivalence:

	Fluent Pro Fluid Management System Hologic, Inc. Proposed Device	**Fluent Fluid Management System (K180825) Hologic, Inc. Predicate Device**
Indications for Use	The Fluent Pro 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 liquid flowing into and out of the uterus while providing drive, control and suction for hysteroscopic morcellators.	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.
Prescription or OTC	Prescription Use	Prescription Use
Product Code	HIG, HIH	HIG, HIH
Regulation Number	21 CFR 884.1700	21 CFR 884.1700
Method of Use	Uterine distention to enable hysteroscopic surgical removal of intrauterine tissue	Uterine distention to enable hysteroscopic surgical removal of intrauterine tissue
Mechanism of Action	Fluid flow with a single peristaltic pump for irrigation and single peristaltic pump for vacuum	Fluid flow with a single peristaltic pump for irrigation and single peristaltic pump for vacuum
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 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.	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.
Inflow Pump Design & Mechanism	Electro-mechanical peristaltic pump	Electro-mechanical peristaltic pump
Pressure Control Range	40-150 mmHg	40-120 mmHg
Maximum Intrauterine Pressure	150 mmHg	120 mmHg
Maximum Inflow Rate	1000 mL/min	650 mL/min

	Fluent Pro Fluid Management System Hologic, Inc. Proposed Device	**Fluent Fluid Management System (K180825) Hologic, Inc. Predicate Device**
Adjustable Suction Settings	Low, Medium, and High	Non-adjustable
Intrauterine Pressure Display	Pressure setting and actual pressure level displayed on the procedure screen	Pressure setting displayed on the procedure screen
Deficit Limit Range	100-2500 mL in increments of 50 mL at start of procedure Deficit can be increased beyond 2500 mL after procedure has started based on physician discretion	100-2500 mL in increments of 50 mL at start of procedure Deficit can be increased beyond 2500 mL after procedure has started based on physician discretion
Fluid Deficit Tracking	Displays Deficit, Deficit Limit, and Total Fluid In	Displays Deficit and Deficit Limit
Deficit Accuracy	± 50 mL under normal use	± 50 mL under normal use
Drive Control Motor speed	2200 ± 270 RPM	2200 ± 270 RPM
MyoSure Operating Modes	System allows operation of TRD control functions with or without operation of the inflow and outflow pumps.	System allows operation of TRD control functions during operation of the inflow and outflow pumps.
Electrical Safety & EMC Testing	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2
Disposable Procedure Kit Sterilization Method	Ethylene Oxide	Ethylene Oxide
Biocompatibility Testing per ISO 10993-1	Yes	Yes

Summary of Testing:
The Fluent Pro Fluid Management System has successfully passed the following performance and simulated-use testing to demonstrate the device is substantially equivalent to the predicate devices and meets design specifications.

Biocompatibility Testing
Biocompatibility testing was performed on the patient contacting materials of the Fluent Pro Fluid Management System in accordance with FDA Guidance *Use of International Standard ISO-10993,*

"Biological evaluation of medical devices – Part 1: Evaluation and Testing within a Risk Management Process," issued on September 8, 2023. The material analysis and testing demonstrate the patient contacting materials are biocompatible and comply with the requirements of ISO 10993-1: 2018 *Biological evaluation of medical devices – Part 1: Evaluation and Testing within a Risk Management Process* for externally communicating, limited exposure, tissue contacting devices:

- ISO 10993-5:2009 – Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 – Biological evaluation of medical devices – Part 10: Tests for skin sensitization
- ISO 10993-11:2017 - Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- ISO 10993-23:2021 - Biological evaluation of medical devices – Part 11: Tests for irritation

Sterilization and Shelf-Life Testing

The Fluent Pro Fluid Management System Procedure Kit is provided as a sterile, single-use device. Sterilization validation was conducted in accordance with ISO 11135:2014. The shelf-life of the disposable product and its packaging integrity were tested in accordance with ASTM F1980, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*, and has a shelf life of 36 months.

Electrical Safety and Electromagnetic Compatibility Testing

The Compass Revolution Colpotomy Device underwent electrical safety and electromagnetic compatibility testing in accordance with the following standards:

- IEC 60601-1:2005 + A1:2012 + A2:2020 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 + A1:2020 – Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests

Performance Testing

The following performance testing was conducted to support the substantial equivalence of the Fluent Pro Fluid Management System to the predicate:

- Intrauterine Pressure Control and Fluid Deficit Bench Testing
- System Mechanical, Hardware, and Electrical Bench Testing
- Software Unit, Integration, and System Testing
- Disposables Pull Force, Flow Rate, and Duty Cycle Bench Testing

Usability Testing

Simulated use testing was performed in accordance with IEC 62366-1:2015 + A1:2020 – Medical Devices – Part 1: Application of Usability Engineering to Medical Devices and FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices," issued February 3, 2016.

Conclusion:

Based on the information submitted in this premarket notification, including the intended use, technological characteristics, and operational use, the Hologic Fluent Pro Fluid Management System has been shown to be substantially equivalent to the predicate device, Fluent Fluid Management System (K180825).