January 17, 2024

Minerva Surgical, Inc.
Michelle Becker
Director of Regulatory Affairs
4255 Burton Drive
Santa Clara, California 95054

Re: K233710
Trade/Device Name: Symphion Operative Hysteroscopy System
Regulation Number: 21 CFR 884.1710
Regulation Name: Closed Loop Hysteroscopic Insufflator With Cutter-Coagulator
Regulatory Class: Class II
Product Code: PGT, HIG
Dated: November 9, 2023
Received: November 20, 2023

Dear Michelle Becker:

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233710

Device Name
Symphion Operative Hysteroscopy System

Indications for Use *(Describe)*
The Symphion Operative Hysteroscopy System and accessories are intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device by distending the uterus with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and providing fluid management through either the closed loop recirculation of filtered distension fluid or non-recirculating/non-filtered distension fluid.

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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Administrative Information

	Subject Device
Trade Name	Symphion Operative Hysteroscopy System
Common Name	Symphion Operative Hysteroscopy System
510(k) #	K233710
510(k) Applicant	Minerva Surgical, Inc. 4255 Burton Drive Santa Clara, CA 95054
Applicant Contact	Michelle Becker Phone: 978-760-1704
Date Prepared	January 16, 2024
Legal Manufacturer	Minerva Surgical, Inc 4255 Burton Drive Santa Clara, CA 95054
Classification #	21 CFR 884.1710
Device Classification Name	Closed loop hysteroscopic insufflator with cutter-coagulator
Product Code	PGT (Insufflator, Hysteroscopic, Fluid, Closed-Loop Recirculation With Cutter-Coagulator, Endoscopic, Bipolar) HIG (Hysteroscopic insufflator)
Classification	Class II *(controller with IV pole and footswitch, recirculating tubing set, resecting device, and Fluid Deficit Readout Accessory)* Class I *(non-recirculating tubing set)*

Legally Marketed Predicate Devices

	Predicate (Primary)	Predicate (Secondary)
Trade Name	IOGYN System	Fluent® Fluid Management System
510(k) #	K141848 (originally cleared through DeNovo K132695)	K180825
510(k) Applicant	IOGYN, Inc 20195 Stevens Creek Blvd, Suite 120 Cupertino, CA 95014	HOLOGIC, INC. 250 Campus Drive Marlborough, MA 01752 USA
Legal Manufacturer	Minerva Surgical, Inc 4255 Burton Drive Santa Clara, CA 95054	HOLOGIC, INC. 250 Campus Drive Marlborough, MA 01752 USA

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

Device Description Summary

The Symphion Operative Hysteroscopy System is comprised of the following:

- Controller with IV Pole and Footswitch
- Resecting Device
- Fluid Management Accessories (INFINITY FMA and EXPRESS FMA)
- Fluid Deficit Readout Optional Accessory

The Symphion Operative Hysteroscopy System provides an integrated control system with bipolar radiofrequency outputs (cut and coagulation) and fluid management through the use of two integrated peristaltic pumps. The Resecting Device is a bipolar radiofrequency device configured for the resection and aspiration of the uterine pathology. Fluid infusion and aspiration of the uterine cavity are controlled by the Controller's peristaltic pumps, in conjunction with the Fluid Management Accessories. The Symphion Controller, with software version 3.0.0 or higher, is designed to be used in either a recirculating (closed-loop) or non-recirculating system configuration. The Fluid Management Accessories are disposable tubing sets and are available in two models, INFINITY FMA and EXPRESS FMA. The FMAs are designed to assist with the delivery, monitoring, and control of the amount of distention media delivered to the uterine cavity when used with the Symphion controller. When the controller is used with the INFINITY FMA, the system components form a closed-loop recirculating system configuration. Alternatively, when the controller is used with EXPRESS FMA, the system components form an open, non-recirculating, system configuration. The INFINITY FMA is designed to be used in all types of intrauterine pathology whereas the EXPRESS FMA, lower cost alternative, may be more suitable for softer type tissues or in procedures that require a shorter resection time such as polypectomy, visual D&C and similar.

The integrated peristaltic pumps are operated by a software pressure control algorithm, specific to use with either INFINITY FMA or EXPRESS FMA configurations, that measures and controls intra-uterine cavity pressure by varying saline infusion and aspiration rates in response to pressure changes during aspiration and tissue resection when using the Resection Device. The Symphion Controller Graphical User Interface has two options for initial set up depending on which FMA configuration is being used during the procedure. There are fluid control settings which allow the user to toggle infusion ON/OFF and to set the target cavity pressure from 45-125mmHg. Subsequent to the initial setup GUI, all procedure and control settings are identical

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regardless of which FMA configuration is being used. The system includes an optional Fluid Deficit Readout accessory device which is an independent saline bag measurement scale to present the user with a digital real-time fluid loss/fluid deficit reading during the Symphion procedure.

Device Intended Use/Indications for Use

The Symphion Operative Hysteroscopy System and accessories are intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device by distending the uterus with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and providing fluid management through either the closed loop recirculation of filtered distension fluid or non-recirculating/non-filtered distension fluid.

Indications for Use Comparison

The Subject Device has the same general Intended Use/Indications for Use as the predicate devices.

Attribute	Subject Device	Predicate (Primary)	Predicate (Secondary)	Equivalent
Trade Name	Symphion Operative Hysteroscopy System	IOGYN System	Fluent® Fluid Management System	NA
Intended Use/Indications for Use	The Symphion Operative Hysteroscopy System is intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device by distending the uterus with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and providing fluid management through **either** the closed loop recirculation of filtered distension fluid **or non-recirculating/non-filtered**	The Symphion System is intended to distend the uterus by filling it with saline to facilitate viewing with a hysteroscope during diagnostic and operative hysteroscopy and provide fluid management through the closed loop recirculation of filtered distension fluid. It is also intended for resection and coagulation of uterine tissue such as intrauterine polyps and myomas using a bipolar resecting device.	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. The Fluent Fluid Management System is designed to be used in operating room, ambulatory surgical center, and physician's office environments. The	YES

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	distension fluid.		gynecologist should be trained in diagnostic and therapeutic hysteroscopy, resection, and removal of gynecological tissue.	

Discussion

Although there are minor differences in how intended use/indications for use are written, the general indication remains the same across the subject device and its predicates. The subject device is a modified version of the primary predicate (Symphion System, closed loop). The modifications include the ability for the user to select a recirculating or nonrecirculating model of the Fluid Management Accessory based on the needs of the patient and dictated by pathology as well as the use of an optional Fluid Deficit Readout accessory.

The intended use/indications use is identical with the primary predicate in all aspects with the exception of the addition of fluid management through a non-recirculating/non-filtered mechanism. The Intended Use/ Indications for Use of secondary predicate (Fluent) does not specify the Fluid management configuration in detail, closed-loop vs non-recirculating. However, the Fluent Fluid Management System is designed with a non-recirculating/ non-filtered fluid management system. The Intended Use of the Subject Device does not specifically mention the optional Fluid Deficit Readout accessory as the Secondary Predicate does describe fluid volume differential monitoring feature. This is due to the fact the Fluid Deficit Readout is an optional accessory to the Symphion Operative Hysteroscopy System, shares the intended use of its parent device, and does not require its own Intended Use.

- The Subject Device, Primary Predicate, and Secondary Predicate are all designed and intended for distension of the uterus through an integrated Fluid Management System.
- The Subject Device and Primary Predicate are designed and intended for resection and coagulation of uterine tissue.
- The Subject Device and its Secondary Predicate both have the ability to monitor fluid for potential absorption.

Therefore, it is concluded the Subject Device's Intended Use/ Indications for Use are similar to the Predicates and does not raise different questions of safety or effectiveness.

Technological Comparison

Attribute	Subject Device	Predicate (Primary)	Predicate (Secondary)	Equivalent
Trade Name	Symphion Operative Hysteroscopy System	IOGYN System	Fluent® Fluid Management System	NA
510(k) #	K233710	K141848 (originally cleared through DeNovo K132695)	K180825	NA

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510(k) Applicant	Minerva Surgical, Inc. 4255 Burton Drive Santa Clara, CA 95054	IOGYN, Inc 20195 Stevens Creek Blvd, Suite 120 Cupertino, CA 95014	HOLOGIC, INC. 250 Campus Drive Marlborough, MA 01752 USA	NA
Controller Specifications	Mode of Operation: Intermittent. Duty Cycle: 30 seconds ON 10 seconds OFF Input: 100-240VAC, 50-60Hz, 700VA Output (Resect): 275W ±20%, 275VMAX, 148 kHz, 200 Ω load Output (Coag): 110W ±20%, 200VMAX, 148 kHz, 200 Ω load Operating Conditions: 60°F to 80°F (16°C to 27°C), 30% to 75% Relative Humidity non-condensing	Identical		YES
Energy Delivered	Bi-Polar Radiofrequency	Identical		YES
Hysteroscopic Fluid Pumps	Peristaltic type, one each Infusion and Aspiration	Identical		YES
Controller User Interface	Digital Touchscreen with both set up steps and procedural controls	Identical		YES
Operating Modes	Diagnostic, Resection	Identical		YES
Intra-Operative Pressure Control	Direct Intra-uterine Pressure measurement	Identical		YES
Pressure Control Limits	45 - 125mmHg	Identical		YES
Default Intrauterine Pressure Setting	45 mmHg	Identical		YES
Infusion Flow Rate	Variable- Infusion flow rate is modulated by the software to control pressure in accordance	Identical		YES

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	with the pressure control specification			
Maximum Intrauterine Pressure	125mmHg	Identical		YES
Key Safety Features (overpressure protection and Venting Mechanism)	The system is designed with both software and hardware overpressure protection in addition to a system warning if/when the pressure set point is increased above 100mmHg.	Identical		YES
Visualization-Recirculation Mode	Resection activation not required. Footswitch actuated recirculation to clear field	Identical		YES
Saline Bag Capacity	One 3 liter saline bag Maximum	Identical		YES
Resection Device (RD) Shaft diameter	3.6mm (~11Fr)	Identical		YES
RD Shaft Working Length	37cm	Identical		YES
RD Electrode Reciprocation	Handpiece motor driven actuation	Identical		YES
RD Reciprocation Type and Travel	Axial, 18mm	Identical		YES
RD Electrode size	2.6mm	Identical		YES
RD Coagulation	Single point, spot coagulation	Identical		YES
Aspiration	Aspiration channel for Tissue/chip removal	Identical		YES
Optics	Endoscopic visualization through the use of the IOGYN Hysteroscope (K123330)	Identical		YES
Hysteroscopic Fluid	Recirculating and non-recirculating tubing sets	Recirculating tubing set	Non-recirculating tubing set	YES

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Circulation Configuration				
Fluid Filtration	Infinity FMA only: Molecular filter	Identical		YES
Tissue collection	Included - Tissue catch (pore size 100 micrometer)	Identical		YES
Pressure Sensor	Direct sensing, Dual Pressure Sensor configuration	Identical		YES
Overall FMA Tubing Length	3 meters	Identical		YES
Tubing Set Infusion Tubing Size	OD: 5/16" ID: 3/16"	Identical		YES
Tubing Set Aspiration Tubing Size	OD: 5/16" ID: 3/16"	Identical		YES
Fluid Deficit Readout Methodology	Real-time, weight based measurement		Identical	YES
Fluid Deficit Accuracy	+/- 50mL		Identical	YES
Maximum Allowable Fluid Deficit Alert Limit function	Automatic, **2450mL** maximum		Automatic, 2500mL maximum	YES
Fluid Deficit Alert Limit Range	**50mL – 2450mL**		100mL – 2500mL	YES
Fluid Deficit Alert Limit Adjustment Interval	50mL (single button press) **100mL (button press w/ hold)**		50mL	YES
FMA (Fluid Pathway) Materials	ABS, PVC, Nylon, Polycarbonate, Polypropylene, Acrylic copolymer, Cyanoacrylate, Viton, Stainless Steel, Silicone, AdvantPure AdvantaFlex, High Density	Identical		YES

	Polyethylene (HDPE), PureWeld, Ethylene Propylene Diene Monomer (EPDM), Polysulfone, Biresin			
Sterility	Disposable tubing sets and resecting devices are provided sterile (10^6 SAL)	Identical		YES
Sterilization Method	Irradiation	Identical		YES

Non-Clinical and/or Clinical Test Summary

As a part of the design control process, The Symphion Operative Hysteroscopy System and accessories were subjected to extensive testing at the system, component, and subassembly levels to ensure that the system performs as intended and that the System met its performance specifications.

Biocompatibility

There was no change to the materials that impacted the existing Biocompatibility testing, therefore no additional biocompatibility testing was required to support the device modification.

- ISO 10993-1:2009, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2002 and 2010, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-11:2006 and 2017, Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12:2007 and 2012, Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- ISO 10993-17:2002, Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
- ISO 10993-18:2005, Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process.

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Software Verification

Software Validation was performed in accordance with the following standards.

- IEC 62304:2015, Medical device software - Software life cycle processes

All results have been deemed acceptable.

Electrical Equipment Safety

The proposed modifications do not impact the applicable Electrical Equipment Safety testing previously conducted for the Symphion Controller.

Applicable Electrical Equipment Safety testing has been conducted for the Symphion Fluid Deficit Readout accessory 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

All results have been deemed acceptable.

Sterilization

The Fluid Management Accessories are provided sterile. Fluid Management Accessories are sterilized by irradiation. Sterilization Validation was previously completed to a sterility assurance level (SAL) of 10-6 per the following standards:

- ANSI/AAMI/ISO 11137-2:2013, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ANSI/AAMI/ISO 11737-1:2006 (R) 2011, Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product
- ANSI/AAMI/ISO 11737-2:2009, Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

All results have been deemed acceptable.

Shelf Life Testing

The is no change in the device packaging for the controller and the fluid management system. The Fluid Management Accessories are labeled with a 1 year shelf life. Shelf Life has been verified in accordance with the following standards:

- ASTM F1980-07(2011), Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM F1886/F1886M-09(R)2013, Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Packaging and Transit Testing

Fluid Deficit Readout packaging and transit has been verified in accordance with the following standards:

- ASTM D4169-22 (2022), Performance Testing of Shipping Containers and Systems

Controller packaging and transit has been verified in accordance with the following standards:

- ASTM D4169-09 (2009), Performance Testing of Shipping Containers and Systems
- ASTM D4332-13 (2013), Conditioning Containers, Packages, or Packaging Components for Testing

FMA packaging and transit testing has been validated in accordance with the following standards:

- ASTM D4169-09 (2009), Performance Testing of Shipping Containers and Systems
- ASTM D4332-13 (2013), Conditioning Containers, Packages, or Packaging Components for Testing

Performance Testing (Special Controls)

Performance tests have been performed for the Fluid Management Accessory and reviewed by FDA in prior submissions (K132695 and K141848), in accordance with Special Controls defined by 884.1710. All results have been deemed acceptable. The related specifications have not been affected by the proposed modification of the device and therefore no new testing is required for the following:

(A) Mechanical testing to assess tensile strength of connections.
(B) Pressure testing that demonstrates the following parameters, including accuracy of the pressure displayed; appropriate detection and response to overpressure conditions; activation of a secondary overpressure relief valve at the maximum safe level; and all accessories within the fluid path meet the pressure requirements.
(C) Fluid delivery volume testing that demonstrates that the maximum fluid volume delivered is below a predefined level.
(D) Flow rate testing.
(E) Simulated use testing.
(F) Filtration testing.
(G) Blood filtration capacity testing.

(H) Tissue collection capacity testing.
(I) Filtrate characterization and testing that demonstrates that the continuous reintroduction of filtrate into the uterus does not pose a safety risk.

Clinical Testing was not required.

Conclusion

The results of non-clinical performance testing demonstrate that the subject device is as safe and effective as the predicate devices to support a substantial equivalence determination.