



March 28, 2018

W.O.M. World of Medicine GmbH
Söeren Markworth
Head of Regulatory Affairs
Salzufer 8
Berlin, 10587
Germany

Re: K173489
Trade/Device Name: GYN-Pump PH304
Regulation Number: 21 CFR§ 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: II
Product Code: HIG, HET
Dated: February 15, 2018
Received: February 27, 2018

Dear Söeren Markworth:

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,

Joyce M. Whang -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

Indications for Use

510(k) Number (if known)
K173489

Device Name
GYN-Pump PH304

Indications for Use (Describe)

The GYN-Pump PH304 is a combined suction and irrigation pump for use in hysteroscopic and laparoscopic interventions. During diagnostic and operative hysteroscopy, the GYN-Pump PH304 is intended to provide liquid distension of the uterus and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus. During diagnostic and therapeutic laparoscopic procedures, the GYN-Pump PH304 is intended to irrigate fluid into and remove fluid from the abdominal cavity.

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 OF SAFETY & EFFECTIVENESS
(Content in accordance with 21 CFR §807.92)

1. General Information

Submitter: W.O.M. WORLD OF MEDICINE GmbH
Salufer 8
10587 Berlin
Germany

Registration Number: 3001556604

Contact Person: Dr. Soeren Markworth
Head of Regulatory Affairs

Phone: +4930-399 81-594
Fax: +4930-399 81-593
E-mail: soeren.markworth@wom.group

Date prepared: 16th of February, 2018

2. Proposed Device

Trade Name: GYN-Pump PH304

Common Name: Pump for Hysteroscopy, Fluid Monitoring System
and Tube Sets;
Laparoscopic irrigation and suction device

Classification Name: Hysteroscopic Insufflator

Regulation Number: 21 C.F.R. § 884.1700

Regulatory Class: II

Product Code: HIG (Insufflator, Hysteroscopic)
HET (Laparoscope, Gynecologic (and Accessories))



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3. Primary Predicate Device

Trade Name:	Aquilex Fluid Control System H112
510(k) Number:	K112642
Classification Name:	Hysteroscopic Insufflator
Regulation Number:	21 C.F.R. § 884.1700
Regulatory Class:	II
Product Code:	HIG (Insufflator, Hysteroscopic)

The Aquilex Fluid Control System H112 has not been subject to a design related recall.

4. Secondary Predicate Device

Trade Name:	LAP-Pump PP110
510(k) Number:	K163320
Classification Name:	Gynecologic laparoscope and accessories
Regulation Number:	21 C.F.R. § 884.1720
Regulatory Class:	II
Product Code:	HET (Laparoscope, Gynecologic (and Accessories))

The LAP-Pump PP110 has not been subject to a design related recall.

5. Device Description

The GYN-Pump PH304 is a microprocessor controlled single roller pump that functions according to the peristaltic principle. It transports sterile irrigation fluid to distend the uterus and provides fluid deficit monitoring during operative hysteroscopy. It is also used to irrigate the abdominal cavity during laparoscopy and provides fluid aspiration. The pump consists of the following main components: a power supply, a power switch, a touch display, a connection for the suction function, a roller wheel, a pump head and a casing. The proposed pump is designed to be used with the Fluid Monitoring Unit PS304 in order to assist with fluid deficit



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monitoring. The Fluid Monitoring Unit PS304 is a component of the GYN-Pump PH304 and together they are a medical electrical system. The pump must be used with the following tube sets:

- Standard Irrigation Tube Set (also referred to as “ST261”)
- Suction Tube Set (one connection, “I”-shape; also referred to as “ST287”)
- Suction Tube Set (two connections, “Y”-shape; also referred to as “ST282”)
- Vacuum Tube Set (also referred to as “ST291”).

6. Intended Use

Please find below a comparison table comparing the indications for use of the GYN-Pump PH304 to both predicate devices. All three devices are designed, developed and manufactured by W.O.M. World of Medicine GmbH.

New Device: GYN-Pump PH304	Primary Predicate Device: AQUILEX FLUID CONTROL SYSTEM H112	Secondary Predicate Device: LAP-Pump PP110
<p>The GYN-Pump PH304 is a combined suction and irrigation pump for use in hysteroscopic and laparoscopic interventions. During diagnostic and operative hysteroscopy, the GYN-Pump PH304 is intended to provide liquid distension of the uterus and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus. During diagnostic and therapeutic laparoscopic procedures, the GYN-Pump PH304 is intended to irrigate</p>	<p>The Aquilex Fluid Control System H112 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.</p>	<p>The LAP-Pump PP110 is a suction and irrigation pump intended for use during diagnostic and/or therapeutic laparoscopic procedures to irrigate fluid into and remove fluid from the abdominal cavity.</p>



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fluid into and remove fluid from the abdominal cavity.		
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The difference between the proposed device and the predicate devices is the following:

- The proposed device can be used for hysteroscopy as well as for laparoscopy, whereas the predicate devices can only be used for a single indication, hysteroscopy or laparoscopy respectively.

Regarding hysteroscopy, the GYN-Pump PH304 has the same indication for use as the primary predicate device. Regarding laparoscopy, the GYN-Pump PH304 has the same indication for use as the secondary predicate device. However, both the subject and predicate devices fall within the same general intended use, which is the delivery and suction of fluid during surgical procedures. Per the FDA guidance “The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)],” issued July 28, 2014, the use of multiple predicates is appropriate when a device has more than one indication within the same general intended use.

7. Comparison of Technological Characteristics

The proposed device as well as the primary and secondary predicate devices are designed, developed and manufactured by W.O.M. WORLD of MEDICINE GmbH. The GYN-Pump PH304 and the primary predicate device Aquilex Fluid Control System H112 have the same or similar technological characteristics in terms of basic operating principle and basic design features. Both pumps are single roller pumps that function according to the peristaltic principle and are to be used with a specifically designed fluid monitoring unit and specially designed tube sets.

Please find below a comparison table comparing the key specifications of the GYN-Pump PH304 to both predicate devices.



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	New Device: GYN-Pump PH304	Primary Predicate Device: AQUILEX FLUID CONTROL SYSTEM H112	Secondary Predicate Device: LAP-Pump PP110
General Device Specifications			
Pump type	Peristaltic, roller	Same	Same
Tube Set Recognition (RFID)	Yes	Same	Same
Automatic Instrument Detection	Yes	Same	n.a.
Suction pressure	High level: 450 mmHg Low level: 225 mmHg	High vacuum pump: 300 to 500 mmHg Low vacuum pump: 225 mmHg	450 mmHg
Medium to be used	Isotonic or hypotonic solutions	Same	Same
Specifications for Hysteroscopy			
Deficit accuracy	+/- 6 %	+/- 10 %	n.a.
Pressure Setting Range	15 - 150 mmHg	40 - 150 mmHg	n.a.
Max. Pressure Setting	Max. 150 mmHg	Same	n.a.
Max. Flow Rate	800mL/min	Same	n.a.



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Flow Setting Range	50-800mL/min	≤800mL/min (not user adjustable)	n.a.
Positive action to increase above 100mmHg	Yes	Yes	n.a.
Hysteroscopy – Important Warnings			
Overpressure Warnings if:			n.a.
a) Intrauterine pressure 10 mmHg above set pressure	Yes	Same	
b) Intrauterine pressure > 150 mmHg	Yes	Same	
c) Intrauterine pressure > 200 mmHg	Yes	Same	
Warning, if Deficit limit has been reached/exceeded	Yes	Same	n.a.
Warning, if high deficit rate is detected	Yes	Same	n.a.
Specifications for Laparoscopy			



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Max. Pressure	500 mmHg (not adjustable)	n.a.	450 mmHg (not adjustable)
Max. Flow Rate	2.0 l/min	n.a.	3.0 l/min (only with special "High-Flow Tube Set"), otherwise 2.0 l/min



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The differences in the technological characteristics of both the proposed device GYN-Pump PH304 and the primary predicate device Aquilex Fluid Control System H112 do not raise different questions of safety and effectiveness. The main differences between both devices are the following:

- The inflow volume for the deficit determination is obtained in different ways. During operative hysteroscopy the primary predicate device determines the used irrigation volume based on the number of rotations of the roller wheel during the procedure. The software controlled calculation of irrigation volume is accomplished by multiplying the flow volume per rotation of the roller wheel (which is a preset amount based on the inner diameter of the tubing set) by the number of rotations of the roller wheel. The fluid monitoring unit PS304 of the proposed device GYN-Pump PH304 utilizes a separate weighting cell allowing for directly weighting of the fluid bags and thus directly weighting the inflow volume. This method improves the accuracy of the fluid deficit measurement to 6%, compared to 10% of the primary predicate device. The fluid deficit determination of the proposed device GYN-Pump PH304 is the same as for the Hysteroscopy Pump HM6, also manufactured by W.O.M. WORLD of MEDICINE GmbH and cleared by FDA under K123732. Because both the subject and predicate devices have fluid deficit monitoring, the difference in deficit determination does not raise different questions of safety and effectiveness.
- In order to provide suction for fluid aspiration, the GYN-Pump PH304 incorporates one vacuum pump with two levels (low and high) while the primary predicate device Aquilex Fluid Control System H112 incorporates two suction pumps, one for each level (low level and adjustable high level). While both low levels are the same, the highest suction level of the primary predicate device is a bit higher compared to the proposed device (500 mmHg versus 450 mmHg); however, this difference does not raise



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different questions of safety and effectiveness, as the risks associated with the suction pressure are the same between the two devices.

- During laparoscopy, the maximal achievable flow rate of 2.0 l/min is the same for both the GYN-Pump PH304 and the secondary predicate device LAP-Pump PP110 when using the same standard irrigation tube set. The LAP-Pump PP110 can achieve a maximal flow rate of 3.0 l/min if the high-flow suction-irrigation tube set available for that device is used. This difference does not raise different questions of safety and effectiveness.
- The maximal system pressure during laparoscopy is 500 mmHg for the GYN-Pump PH304 and 450 mmHg for the secondary predicate device LAP-Pump PP110. With these system pressures, both pumps are able to reach the same desired flow rate, which is maximal 2.0 l/min when using the standard irrigation tube set for both pumps. The system pressure cannot be set by the user in either device. There is no distention of a body cavity with irrigation, and therefore no pressure build up within a body cavity is measured for either device. Both devices have the same risks associated with the irrigation pressure. Therefore, this difference does raise different questions of safety and effectiveness.

The differences outlined were evaluated through performance testing to demonstrate the safety and effectiveness of the GYN-Pump PH304.

8. Performance Data

Software

The software was developed, tested, and verified in accordance with the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and in accordance with the following standard:

- IEC62304:2006 - Medical Device Software – Software Life Cycle Processes.



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Design verification testing of the GYN-Pump PH304 demonstrates that the device performs as intended.

Electrical safety and electromagnetic compatibility

Electrical safety and electromagnetic compatibility testing was performed in accordance to the following standards:

- AAMI ANSI ES60601-1: 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-1-2:2014 - Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests;

Biocompatibility

The irrigation tube set has indirect contact with the patient via the irrigation fluid introduced into the patient and is classified as external communicating device in contact with tissue/bone/dentin for a limited time (≤ 24 h) in accordance with *AAMI/ANSI/ISO 10993-1:2009*. The irrigation tube set for the GYN-Pump PH304 is the same tube set as the irrigation tube set for the secondary predicate device LAP-Pump PP110 cleared by FDA under K163320 on the 21st of March, 2017, manufactured by W.O.M. World of Medicine GmbH. Thus, as the irrigation tube set is identical, biocompatibility data from the predicate device submission is leveraged for the irrigation tube set of the GYN-Pump PH304. The following tests for biocompatibility were performed on the irrigation tube set:

- ISO 10993-1 - Biological evaluation of medical devices- Evaluation and testing within a risk management system;
- ISO 10993-5:2009 - Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity; and



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- ISO 10993-10:2010 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- ISO 10993-11:2006 - Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.

Sterilization

In addition, sterilization validation on the tube set has been performed in accordance with:

- ISO 11135-1:2015 - Sterilization of health care products – Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices;
- ISO 14937:2009 - Sterilization of health care products - General criteria for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices; and
- ISO 10993-7:2008 - Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) data shows that the limit of EO < 4 mg and ECH < 5 mg after 10 days of aeration (gas release) that remain on the tube set will not be exceeded. The sterility assurance level (SAL) was $\leq 10^{-6}$.

Shelf Life

The shelf life of the tube set is 3 years. To support this shelf life, simulated distribution and real-time aging was conducted on the tube sets for a duration of 5 years at ambient conditions. Testing included package and product integrity in accordance with *ISO11607-1:2006 - Packaging for terminally sterilized medical devices* and simulated distribution testing per ASTM D4169, ASTM D642, ASTM D5276 and ISO 2233. In addition, performance of the tubes was demonstrated after simulated distribution and aging through air leak testing, RFID content, and connector strength testing. All samples met predefined acceptance criteria after 5 years of real time aging.



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Performance Testing - Bench

Two bench tests were performed to demonstrate that the proposed device GYN-Pump PH304 is safe and effective.

Comparative Bench test – Fluid deficit measurement

First, a comparative bench test was conducted to demonstrate that the proposed device GYN-Pump PH304 can measure fluid deficit accurately as compared to the primary predicate device, Aquilex Fluid Control System H112. In the test, fluid was dispensed through the system, and the fluid deficit calculated by the device was compared to a manual measurement. Results demonstrated the subject device met predefined acceptance criteria, and that the subject device deficit measurement performed as well as the predicate Aquilex Fluid Control System H112.

Pressure Regulation

Second, a bench test was performed to demonstrate the performance of the pressure regulation of the GYN-Pump PH304. The GYN-Pump PH304 was connected to a model system and cycled through a representative range of flow rates and pressures under expected use conditions, including steady state and when outflows are open and closed. Pressure was continuously monitored and recorded. Results demonstrated that the GYN-Pump PH304 met all predefined acceptance criteria for pressure maintenance.

9. Conclusion

The GYN-Pump PH304 has the same intended use and the same basic technological characteristics of the primary predicate device Aquilex Fluid Control System H112 and the secondary predicate device LAP-Pump PP110. The differences between the GYN-Pump PH304 device and the predicate devices do not raise different questions of safety and effectiveness. Performance testing, including electrical safety, electromagnetic compatibility, sterilization validation, biocompatibility, shelf life, and bench testing has demonstrated that the GYN-Pump PH304 is as safe and effective as the predicates. Therefore, the GYN-Pump is substantially equivalent to the predicate devices.