February 5, 2018

W.O.M. World of Medicine GmbH
% Susanne Raab
Regulatory Consultant
Susanne Raab
Guenthersburgallee 75
60389 Frankfurt
GERMANY

Re: K172040
Trade/Device Name: Aquilex® Fluid Control System AQL-100S
Regulation Number: 21 CFR 884.1700
Regulation Name: Hysteroscopic insufflator
Regulatory Class: Class II
Product Code: HIG
Dated: January 3, 2018
Received: January 10, 2018

Dear Susanne Raab:

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

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)*
K172040

Device Name
Aquilex® Fluid Control System AQL-100S

Indications for Use *(Describe)*

The Aquilex® Fluid Control System AQL-100S is intended to provide fluid 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.

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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Aquilex® Fluid Control System AQL-100S
Special 510(k) Premarket Notification

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information:

Submitter:
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Date Prepared: January 30, 2018

Proposed Device:

Trade Name: Aquilex® Fluid Control System AQL-100S
Common Name: Hysteroscopic Insufflator, Fluid Monitoring System and Tube Sets
Classification Name: Hysteroscopic Insufflator and Accessories
Regulation Number: 21 CFR 884.1700
Regulation Name: Hysteroscopic Insufflator
Regulatory Class: II
Product Code: HIG

Predicate Devices:

Primary Predicate Device:

Trade Name: Aquilex Fluid Control System H112
510(k) Number: K112642
Applicant: W.O.M. WORLD OF MEDICINE GmbH
Regulation Number: 21 CFR 884.1700
Regulatory Class: II
Product Code: HIG

Aquilex® Fluid Control System AQL-100S
Special 510(k) Premarket Notification

Secondary Predicate Device:

Trade Name:	Hysteroscopy Pump HM6
510(k) Number:	K123732
Applicant:	W.O.M. WORLD OF MEDICINE GmbH
Regulation Number:	21 CFR 884.1700
Regulatory Class:	II
Product Code:	HIG

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

Device Description:

The Aquilex® Fluid Control System AQL-100S is a modified version of the primary predicate device, Aquilex Fluid Control System H112 (K112642). The proposed device is a microprocessor-controlled device that consists of the following two main components: (1) an irrigation pump unit including suction pumps (AQL-110P) and (2) and fluid monitoring unit (AQL-100CBS) that are to be placed on a roller stand. The irrigation pump unit (AQL-110P) of the Aquilex® Fluid Control System AQL-100S is a microprocessor-controlled device that functions according to the peristaltic principle and consists of the following components: (1) a casing, (2) a power switch, (3) a power supply, (4) mains cable, (5) a roller wheel, (6) a pump head, (7) suction pumps, (8) various setting keys and (9) display elements. The irrigation pump unit (AQL-110P) is to be used with specially designed single use irrigation and outflow tube sets that are delivered sterile (AQL-110 and AQL-111). In addition, the suction pumps of the irrigation pump unit are to be used with specially designed non-sterile vacuum tube sets (AQL-114). The fluid monitoring unit (AQL-100CBS) consists of the following main components: (1) two scale units, (2), a bag holder, (4) a bag deflector, (5) a container holder, and (6) a roller wheel base. The irrigation pump unit of the proposed device is only operational in conjunction with the fluid monitoring unit.

Intended Use / Indication for Use:

The Aquilex® Fluid Control System AQL-100S is intended to provide fluid 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.

Substantial Equivalence and Comparison of Technological Characteristics:

The proposed device, Aquilex® Fluid Control System AQL-100S, is substantially equivalent to the predicate devices, Aquilex Fluid Control System H112 (K112642) and Hysteroscopy Pump HM6 (K123732). As stated above the proposed device, Aquilex® Fluid Control System AQL-100S, is a modified version of the primary predicate device, Aquilex Fluid Control System H112.

The proposed device, Aquilex® Fluid Control System AQL-100S, and the predicate devices, Aquilex Fluid Control System H112 and Hysteroscopy Pump HM6, are all intended to provide fluid 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 proposed device and the predicate devices have the same intended use.

Furthermore, tThe proposed device, Aquilex® Fluid Control System AQL-100S, and the predicate device, Aquilex Fluid Control System H112 and Hysteroscopy Pump HM6, use the same basic operating principles and incorporate the same basic design. All three devices incorporate the following main components: (1) irrigation pump, (2) fluid monitoring unit, (3) irrigation and outflow tube sets.

The modification to the Aquilex® Fluid Control System AQL-100S in comparison to the primary predicate device, Aquilex Fluid Control System H112, do not raise different questions of safety and effectiveness. The differences between both devices are the following:

- Incorporation of a separate bag scale into the fluid monitoring unit of the Aquilex® Fluid Control System AQL-100S to calculate the inflow volume, whereas the Aquilex Fluid Control System H112 determines the inflow volume based on the number of rotation of the roller wheel.

- Change in design of the cart to allow for a mounting of the bag scale and addition of bag deflector.

- Incorporation of a fluid bag and container change detection feature into the Aquilex® Fluid Control System AQL-100S.

- Increase in the suction pressure of the low suction pump from 125 to 225 mmHg.

- The inflow tubing AQL-110 of the primary predicate device has been slightly modified.

- The filter of the reusable vacuum tubing is manufactured by a different supplier.

With regards to the incorporation of an additional bag scale, the proposed device, Aquilex® Fluid Control System AQL-100S, is substantially equivalent to the secondary predicate device, Hystersocopy Pump HM6, that also utilizes a separate scale for determination of the inflow volume.

With regards to the incorporation of a separate bag scale into the fluid monitoring unit to determine the inflow volume and change in design of the cart to allow for a mounting of the bag scale, the proposed device, Aquilex® Fluid Control System AQL-100S, is substantial equivalent to the secondary predicate device, Hysteroscopy Pump HM6. Like the proposed device, Aquilex® Fluid Control System AQL-100S, the secondary predicate device, Hysteroscopy Pump HM6, incorporates a separate scale to determine the inflow volume for calculation of the fluid deficit.

With regards to the fluid bag change detection feature is substantially equivalent to the secondary predicate device, Hysteroscopy Pump HM6, that incorporates the same feature. The bag deflector was added to the fluid monitoring unit of the proposed device, Aquilex® Fluid Control System AQL-100S, to protect the bag scale from fluid.

The increase in the suction pressure of the suction pump from 125 to 225 mmHg, that was implemented due to end user demand to ensure fluid suction even if the tubing is draped over the patient's leg.

The modifications that were made on the inflow tubing AQL-110 are minor and have not changed the material, suppliers and manufacturing method.

Performance Data:

Electrical Safety and Electromagnetic Compatibility Testing:

Electrical safety and electromagnetic compatibility testing was performed by independent laboratories and the test results demonstrate that the proposed device conforms to the below standards:

- IEC 60601-1 2005/(R)2012 and A1: 2012, C1:2009/(R)2012 andA2: 2010/(R)2012 (consolidated text); and

- IEC 60601-1-2 Fourth Edition: 2014.

Software:

The software was considered as major level of concern in accordance with the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Software verification and validation testing of the Aquilex® Fluid Control System AQL-100S demonstrates that the device performs as intended. It was developed, tested and verified in accordance with the above FDA guidance document and in accordance with the following standard:

- IEC 62304 First Edition 2006-05.

Biocompatibility:

Biocompatibility testing was performed in accordance with:

- AAMI/ANSI/ISO 10993-1 Fourth Edition 2009-10-15 - Biological evaluation of medical devices- Evaluation and testing within a risk management system;
- ISO 10993-5: 2009 (R) 2014 - Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-10 Third Edition 2010-08-01 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization; and
- ISO 10993-11 Second Edition 2006-08-15- Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity;
- ISO 10993-12:2007 Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials.

Sterilization and Shelf Life:

Sterilization validation was performed in accordance with:

- ISO 10993-7 Second Edition 2008-10-15- Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals;
- AAMI TIR 28 2009/(R)2013, Product adoption and process equivalency for ethylene oxide sterilization;

- ISO 11135-1:2007 - 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 Second Edition 2009-10-15- 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.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) data shows that the limit of EO < 4 mg and ECH < 5 mg after 4 days of aeration (gas release) that remain on the tube set will not be exceeded. As a result of the sterilization validation, a sterility assurance level (SAL) $\leq$ 10^{-6} in accordance with ANSI/AAMI/ISO 11135-1 was achieved. Package and product integrity of the tube sets were tested in accordance with ISO11607-1 - Packaging for terminally sterilized medical devices and ASTM-F1980:2002 - Standard for accelerated aging of sterile medical device packages.

Bench Testing:

Bench testing was performed to demonstrate that the fluid deficit determination of the proposed device, Aquilex® Fluid Control System AQL-100S, using a bag and container scale, is substantially equivalent to that of the secondary predicate device, Hysteroscopy Pump HM6, in terms of accuracy.

Conclusion:

The Aquilex® Fluid Control System AQL-100S is substantially equivalent to the predicate devices: Aquilex Fluid Control System H112 and Hysteroscopy Pump HM6.