K112642

WORLD OF MEDICINE

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Aquilex Fluid Control System H112
Special 510(k) Premarket Notification

510(k) SUMMARY OF SAFETY & EFFECTIVENESS

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Date Prepared: January 28, 2012

Trade Name: Aquilex Fluid Control System H112

Common Name: Hysteroscopic Insufflator, Fluid Monitoring System and Tube Sets

Classification Name: Hystersoscopic Insufflator and Accessories under 21 C.F.R. 884.1700

Regulatory Class: II

Product Code: HIG

Predicate Devices: IUR Fluid Management System, W.O.M. WORLD OF MEDICINE AG, K031616

FLOSIMPLE Arthroscopy Pump A120, W.O.M. WORLD OF MEDICINE AG, K062380

Flo-Stat Fluid Monitoring System, Gynecare Innovation Center, K083211

Karl Storz Hamou Endomat, Karl Storz Endoscopy-America, K936231

Device Description:

The Aquilex Fluid Control System H112 is a microprocessor controlled device that consists of the following two main components: (1) an irrigation pump unit and (2) and fluid monitoring unit that are to be placed on a special roller stand. The irrigation pump unit is a single roller pump that functions according to the peristaltic system. It is to be used with specially designed single use irrigation and outflow tube sets that are supplied sterile. The irrigation pump unit of the proposed device is only operational in conjunction with the fluid monitoring unit. Strict fluid intake and output surveillance is therefore ensured during the entire procedure.

Intended Use:

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.

Summary of Similarities and Differences in Technological Characteristics:

The Aquilex Fluid Control System H112 ("the Aquilex System") and the predicate devices use the same or similar basic operating principles and incorporate the same or similar basic design including materials. Specifically, the Aquilex System and the predicate devices IUR Fluid Managment System ("the IUR System") and Flo-Stat Fluid Monitoring System ("the Flo-Stat System") incorporate the following main components: (i) an irrigation pump, (ii) a fluid monitoring unit, and (iii) an irrigation tube set. Furthermore, like the predicate irrigation pump Karl Storz Hamou Endomat, the Aquilex System is designed with a vacuum function that is to be used with specially designed vacuum tube sets.

The irrigation pumps of the Aquilex System and the predicate devices are all electro-mechanical and microprocessor controlled devices that function according to the peristaltic principle. Both the Aquilex System and the predicate devices utilize pressure sensors to monitor the intrauterine pressure. To achieve the desired pressure within the cavity, the pressure sensor of both the Aquilex System and the predicate devices are connected to a processor that controls the speed of the roller wheel and thus the volume of fluid that is delivered into the cavity. Specifically, the Aquilex System and the predicate devices Karl Storz Hamou Endomat and FLOSIMPLE Arthroscopy Pump A120 incorporate one pressure sensor that is located at the pump head. The maximum selectable pressure of the Aquilex System (150 mmHg) is similar to the maximum pressure settings of the predicate devices: Karl Storz Hamou Endomat (200 mmHg), IUR System (120 mmHg) and Flo-Stat System (100 mmHg). The irrigation tube set of the Aquilex System is identical in design to the irrigation tube set of the IUR System except for minor design changes to the pressure chamber, the incorporation of a clip socket and tubing connector as new components and the shortening of the overall length of the inflow tubing. In addition, the irrigation tube set is similar in design to the irrigation tube set of the FLOSIMPLE Arthroscopy Pump A120 (e.g. incorporation of clip socket and tubing connector, design of pressure chamber with one membrane).

The fluid monitoring units of the Aquilex System and the predicate devices IUR System and Flo-Stat System are electro-mechanical, microprocessor controlled devices that monitor the amount of delivered irrigation solution and compare it with the volume of the secretions returned to the container by means of a mass/volume differential measurement. To determine the fluid deficit during hysteroscopic procedures the Aquilex System measures the inflow volume using the rotation of the roller wheel and the outflow volume by means of a weighing scale, whereas the predicate devices IUR System and Flo-Stat System utilize a scale to measure both the inflow and outflow volume.

Finally, both the Aquilex System and the predicate devices are designed with the same or similar setting keys, display elements and safety features (e.g. active pressure reduction, overpressure warnings and fluid deficit warnings).

Substantial Equivalence:

The Aquilex Fluid Control System H112 is substantially equivalent to the IUR Fluid Management System (K031616), the Flo-Stat Fluid Monitoring System (K083211) the Karl Storz Hamou Endomat (K936231) and FLOSIMPLE Arthrsocopy Pump A120 (K062380). Specifically, the Aquilex Fluid Control System H112 and the predicate devices are intended to provide liquid distension of the uterus during

diagnostic and operative hysteroscopy (Karl Storz Hamou Endomat), and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus (IUR Fluid Management System and Flo-Stat Fluid Monitoring System).

In addition, the Aquilex Fluid Control System H112 and the predicate devices use the same or similar basic operating principles and incorporate the same or similar basic design features including materials. The differences between the Aquilex Fluid Control System H112 and the predicate devices do not raise new questions of safety and effectiveness. The use of a single pressure sensor for pressure monitoring and regulation of the irrigation pump is substantially equivalent to the Karl Storz Hamou Endomat and FLOSIMPLE Arthroscopy Pump A120. The maximum pressure of the Aquilex System has been shown to be substantially equivalent to the predicate device IUR Fluid Management System, Karl Storz Hamou Endomat and other cleared hysteroscopic pumps. The incorporation of a vacuum function into the irrigation pump of the Aquilex Fluid Control System H112 is substantially similar to the vacuum function of the predicate device Karl Storz Hamou Endomat. Furthermore, the determination of the inflow volume using the rotation of the roller wheel has been demonstrated to be substantially equivalent to the fluid deficit determination of the predicate devices IUR Fluid Management System and Flo-Stat Fluid Management System and other cleared hysteroscopic fluid management systems. The irrigation tube set of the Aquilex Fluid Control System H112 is substantially similar to the irrigation tube set of the predicate devices IUR Fluid Management System, FLOSIMPLE Arthroscopy Pump A120 and other cleared tube sets manufactured by W.O.M. Finally, bench, sterility, and packaging test results demonstrate that the differences between the Aquilex Fluid Control System H112 and the predicate devices do not raise new questions of safety and effectiveness.

Performance Testing:

Testing was performed with the irrigation pump of the Aquilex Fluid Control System H112 to demonstrate the alignment of the uterine model pressure and pump display pressure under steady state conditions. The test results show that the pump display and model pressure measurements are equal within the accuracy capability of the pressure display (5 mmHg increments) throughout the entire pressure range of the irrigation pump.

In addition, bench testing has been conducted to demonstrate that the flow and pressure regulation algorithm of the Aquilex Fluid Control System H112 is designed to compensate for the intra-cavity pressure changes that result from activation and deactivation of the MyoSure morcellator when used with the high vacuum pump.

The test results demonstrate the ability of the Aquilex System to effectively compensate for pressure changes resulting from aspiration when the MyoSure morcellator is activated across the full range of possible system settings. In detail, the test results show that pressure losses that occurred after activation of the morcellator never fell to a critical point, thus preventing the collapse of the uterus, and that the initial short-term pressure losses were compensated effectively. Moreover, the test results show that a recovery to stable pressures was reached within a few seconds after the morcellator was deactivated.

Finally, bench testing was performed with the Aquilex Fluid Control System H112 and the inflow tube sets to measure the accuracy of the fluid deficit determination. The test results show that the deficit accuracy in each test run was within a range that is substantially equivalent to the accuracy of the predicate devices and other cleared hysteroscopic fluid monitoring systems.

The Aquilex Fluid Control System H112 has been tested and complies with the international standard IEC 60601-1, General Requirements for Medical Electrical Equipment - Part 1: General Requirements for Safety and IEC60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

ETO sterility validation of the tube sets was performed in accordance with ISO 11135-1, Sterilization of health care products –Ethylene Oxide – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices; and ISO 10993-7, 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 < 5 mg / 10 days and ECH < 5 mg / 10 days that remain on the tube set will not be exceeded. A sterility assurance level (SAL) of $\leq 10^{-6}$ is achieved.

Package and product integrity of the tube sets were tested in accordance with ISO11607-1, Packaging for Terminally Sterilized Medical Devices and ASTM-F-1980-02, Standard for Accelerated Aging of Sterile Medical Device Packages.

Conclusion:

The Aquilex Fluid Control System H112 is substantially equivalent to the IUR Fluid Management System (K031616), the Flo-Stat Fluid Monitoring System (K083211), the Karl Storz Hamou Endomat (K936231) and the FLOSIMPLE Arthrsocopy Pump A120 (K062380). Specifically, the proposed device has the same intended use as the predicate devices. In addition, the Aquilex Fluid Control System H112 and the predicate devices use the same or similar basic operating principles and

incorporate the same or similar basic design features including materials. The differences between the Aquilex Fluid Control System H112 and the predicate devices do not raise new questions of safety and effectiveness. Finally, bench, sterility and packaging testing demonstrate that the differences between the Aquilex Fluid Control System H112 and the predicate devices do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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FEB - 6 2012

Re: K112642
Trade/Device Name: Aquilex Fluid Control System H112
Regulation Number: 21 CFR§ 884.1700
Regulation Name: Hysteroscopic insufflator
Regulatory Class: II
Product Code: HIG
Dated: January 31, 2012
Received: February 1, 2012

Dear Ms. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

WORLD OF MEDICINE.
Fluid Control System H112
Special 510(k) Premarket Notification

INDICATIONS FOR USE STATMENT

510(k) Number (if known): K112642

Device Name: Aquilex Fluid Control System H112

Indications for Use:

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.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112642