DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 21, 2017

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

Re: K163320
Trade/Device Name: LAP-Pump PP110
Regulation Number: 21 CFR 884.1720
Regulation Name: Gynecologic laparoscope and accessories
Regulatory Class: Class II
Product Code: HET
Dated: March 7, 2017
Received: March 8, 2017

Dear Dr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education 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. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education 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,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163320

Device Name
LAP-Pump PP110

Indications for Use *(Describe)*
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.

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

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Date prepared: 7th of March, 2017

2. Proposed Device

Trade Name:	LAP-Pump PP110
Common Name:	Suction and Irrigation pump for Laparoscopy
Classification Name:	Gynecologic laparoscope and accessories
Regulation Number:	21 C.F.R. § 884.1720
Regulatory Class:	II
Product Code:	HET

3. Predicate Devices

Primary Predicate Device

Trade Name:	LAP-Wave 3000 (P07)
510(k) Number:	K990732
Classification Name	Gynecologic laparoscope and accessories
Regulation Numer	21 C.F.R. § 884.1720
Regulatory Class	II
Product Code	HET

Secondary Predicate Device

Trade Name:	KSEA UNIVERSAL LAPAROMAT LAPAROSCOPIC SUCTION AND IRRIGATION PUMP
510(k) Number:	K010569
Classification Name	Laparoscope, General & Plastic Surgery
Regulation Numer	21 C.F.R. § 876.1500
Regulatory Class	II
Product Code (Classification)	GCJ
Product Code (Subsequent)	BTA

4. Device Description

The LAP-Pump PP110 is a suction and irrigation pump for use during laparoscopic procedures. The irrigation and suction functions are used to facilitate the removal of debris and fluids during laparoscopy. The pump consists of the following main components: : (1) a power supply, (2) a power switch, (3), a START/STOP button for the irrigation function, (4), a START/STOP button for the suction function, (5) a roller wheel, (6) a pump head, (7) suction pump and (8) a casing. The pump is a microprocessor controlled single roller pump that functions according to the peristaltic principle and is to be used with specially designed sterile, single use irrigation tube sets with or without hand piece, a sterile outflow tube set

and a vacuum tube set. The pump is designed to be mounted on a pole/tripod, or can be placed in an equipment rack.

5. Intended Use

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.

6. Comparison of Technological Characteristics

Primary Predicate Device

The predecessor product of the proposed device LAP-Pump PP110 is the LAP Wave 3000 (P07). The LAP-Wave 3000 (P07) was originally cleared under K990732 and is the primary predicate device for the LAP-Pump PP110. Both pumps are designed, developed and manufactured by W.O.M. WORLD of MEDICINE GmbH. They incorporate the same basic design. Specifically, both the LAP-Pump PP110 and the LAP-Wave 3000 (P07) are pump systems for use during laparoscopic procedures. They are microprocessor controlled single roller pumps that function according to the peristaltic principle and are to be used with specially designed tube sets.

The differences in the technological characteristics of both the proposed device LAP-Pump PP110 and the primary predicate device LAP-Wave 3000 (P07) are minor and do not raise new questions of safety and effectiveness. The main differences between the LAP-Pump PP110 and the LAP-Wave 3000 (P07) are the following:

- The LAP-Pump PP110 incorporates a suction pump that is to be used with a non-sterile vacuum tube set. The LAP-Wave 3000 (P07) does not have a vacuum pump, which means a separate vacuum pump or the central vacuum connection of the hospital had to be used when needed.
- The LAP-Pump PP110 is designed with a radio frequency identification (RFID) transponder technology tube set recognition function that controls the proper

position of the Inflow Tube Set and eliminates accidental reuse of an Inflow Tube Set by invalidating the tube set after the irrigation process has been started.

- The LAP-Pump PP110 includes a greater variety of tube sets. For the LAP-Pump PP110 the following tube sets are available as accessories: standard irrigation tube set, high-flow suction-irrigation tube set with hand piece, suction tube set and vacuum tube set. The LAP-Wave 3000 (P07) featured only a standard irrigation tube set which can be connected to a standard hand piece.

Secondary Predicate Device

The KSEA UNIVERSAL LAPAROMAT LAPAROSCOPIC SUCTION AND IRRIGATION PUMP (hereafter referred to as „Laparomat“) was originally cleared under K010569 and is the secondary predicate device for the LAP-Pump PP110. Both pumps incorporate a similar basic design. Specifically, both the LAP-Pump PP110 and the Laparomat are pump systems for use during laparoscopic procedures. They are microprocessor controlled pumps that provide irrigation and suction functions and are to be used with specially designed tube sets.

The differences in the technological characteristics of both the proposed device LAP-Pump PP110 and the secondary predicate device Laparomat are minor and do not raise new questions of safety and effectiveness. The main differences between the LAP-Pump PP110 and the Laparomat are the following:

- The LAP-Pump PP110 is designed with a radio frequency identification (RFID) transponder technology tube set recognition function that controls the proper position of the Inflow Tube Set and eliminates accidental reuse of an Inflow Tube Set by invalidating the tube set after the irrigation process has been started.
- The LAP-Pump PP110 transports the irrigation fluid via the peristaltic principle using a roller wheel, while the Laparomat uses an impeller for irrigation fluid transportation.
- The irrigation tube sets of both devices have a different design with respect to the fluid transportation mechanism. The irrigation tube sets of the LAP-Pump PP110 feature a segment which is intended to be inserted around the roller wheel of the

pump, while the irrigation tube sets of the Laparomat feature an impeller segment which is intended to be connected to the connection site of the pump.

7. Performance Data

Electrical safety and electromagnetic compatibility testing was performed by independent laboratories in accordance with 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;
- IEC60601-1-2:2007 - Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

Test results demonstrate that the proposed device conforms to the above standards.

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:

- IEC 62304:2006 - Medical Device Software – Software Life Cycle Processes.

Design verification testing of the LAP-Pump PP10 demonstrates that the device performs as intended and that the performance does not raise new questions of safety and effectiveness.

ETO sterilization validation on the tube sets was performed in accordance with the below standard:

- 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 14937:2009 - 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 ≤ 10^{-6}. Package and product integrity of the tube sets were tested in accordance with *ISO 11607-1 - Packaging for terminally sterilized medical devices and ASTM-F-1980:2002 - Standard for accelerated aging of sterile medical device packages*.

Biocompatibility testing was performed on the tube sets in accordance with:

- ISO 10993-1 - Biological evaluation of medical devices- Evaluation and testing within a risk management system;
- ISO 10993-5 - Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity;
- ISO 10993-10 - Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization; and
- ISO 10993-11 - Biological evaluation of medical devices -- Part 11: Tests for systemic toxicity.

Finally, complete testing was performed to demonstrate safety and effectiveness of the proposed device LAP-Pump PP110. As the flow rate of 3 l/min as the main function of the predicate and the proposed device is the same, no comparative testing was performed. Instead, the performance and safety features of the proposed device are demonstrated.

8. Conclusion

Based on the similar intended use compared to the primary predicate device as well as the same intended use compared to the secondary predicate device, the same or similar basic technological characteristics and performance testing, the LAP-Pump PP110 is substantially equivalent to the predicate devices LAP-Wave 3000 (P07) (K990732) and Laparomat (K010569). The differences between the proposed device and the predicate devices do not raise new questions of safety and effectiveness.