JUL 23 1999

K990732

H. Summary of Safety and Effectiveness - 510(k) Summary

W.O.M. GmbH
Michael McGrail, Manager, Regulatory Affairs
Kaiserin-Augusta-Allee 113
D-10553 Berlin
Germany.

Proprietary Name: LAP-WAVE 3000 (P07)
Common Name: Laparoscopic Irrigation Pump

The LAP-WAVE 3000 (P07) (K990732) is an irrigation pump for minimally invasive surgery. It is used to facilitate the removal of debris and fluids during laparoscopic procedures by irrigation. Irrigation fluid is transported from the fluid container to the instrument inserted in the patient by means of a roller-wheel pump at the device and a disposable PVC tubing set. A trumpet valve instrument (not provided with device) is used to manipulate the flow of fluid into the patient. A pressure sensor at the device is used to regulate pressure at the instrument (trumpet valve). Irrigation is initiated by opening the instrument and discontinued by closing the instrument. Also, a tubing set for connection to a central suction system is provided with the device to allow for removal of the fluid from the patient.

The LAP-WAVE 3000 (P07) described in this notification is substantially equivalent to the device Surgipump, K935763, also manufactured by W.O.M. GmbH. The LAP-WAVE 3000 (P07) incorporates the same design features as the Surgipump, K935763. The only differences lie in the following:

1. The LAP-WAVE 3000 (P07) does not provide suction. The device is for irrigation only.

2. The LAP-WAVE 3000 (P07) incorporates a pressure sensor which is used to regulate pressure at the instrument (trumpet valve). Irrigation is initiated by opening the instrument and discontinued by closing the instrument. The maximum pressure at the instrument is restricted to 600 mm Hg. This pressure restriction at the instrument is intended to protect the tubing set and instrument from excessive pressure only. This feature is not a safety feature of the device and no intraabdominal pressure measurement is performed. The Surgipump, K935763 did not incorporate pressure regulation at the instrument, rather the irrigation function was activated and deactivated using the manual control or foot pedal.

3. The flow performance of the LAP-WAVE 3000 (P07) has been increased to 3 L/min.

4. The casing of the device has been modified to allow for mounting on a roller-wheel stand.

During operative laparoscopy, suction/irrigation systems are used for the maintenance of a clear operative area, replacing the function of the sponge and suction used during classic laparatomy. In the literature (1) (2) (3) (4) (5) (6) (7) (8), the requirement for thorough lavation of the abdomen is established. Only with continual rinsing is the surgeon ensured a clear operative area, a prerequisite for the safe performance of laparoscopic procedures.

Suction/irrigation systems for laparoscopy have been supplied by various manufacturers for the past 25 years. Complications have not been reported during the many years of use of these systems in almost every operative laparoscopic procedure.

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Based on extensive experience with suction/irrigation systems in operative laparoscopy without complications, the determination may be made that this procedure is safe and effective. The performance specifications of the LAP-WAVE 3000 (P07) correspond with the requirements established in the literature.

REFERENCES

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2. Buess G.: Endoskopie. Deutscher Ärtze Verlag, Köln, 245-268, 1990

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Signed: M. McGrail

Michael McGrail
Agent for W.O.M. GmbH

2 June 1999
Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1999

W.O.M. GmbH
c/o Mr. Michael McGrail
Regulatory Consultant
194 Branch Street
Mansfield, Massachusetts 02048

Re: K990732
Trade Name: LAP-WAVE 3000 (PO7)
Regulatory Class: II
Product Code: HET
Dated: June 9, 1999
Received: June 15, 1999

Dear Mr. McGrail:

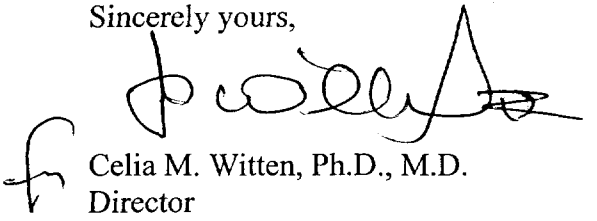
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPICANT: W.O.M. GmbH

510(K) NUMBER (if known): K990732

DEVICE NAME: LAP-WAVE 3000 (P07)

INDICATIONS FOR USE:

The LAP-WAVE 3000 (P07) is an irrigation pump for minimally invasive surgery. It is used to facilitate the removal of debris and fluids during laparoscopic procedures by irrigation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990732

Prescription Use X
(Per 21 CFR 801.109)