K983889

JAN 14 1999

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: HYS-Surgiflator 150P
Common Name: Hysteroscopic Insufflator

The HYS-Surgiflator 150P is a hysteroscopic insufflator intended to distend the uterus by fillng the uterine cavity with a gas to facilitate viewing with a hysteroscope (21 C.F.R. § 884.1700).

The HYS-Surgiflator 150P described in this notification is substantially equivelant to the Hysteroflator OP, K922632/B, manufactured by W.O.M. GmbH. The HYS-Surgiflator OP incorporates the same design features as the Hysteroflator OP K922632/B. The only differences lie in the following:

1. The max. intrauterine pressure has been reduced from 200 mm Hg to 150 mm Hg
2. The HYS-Surgiflator 150P allows for preselection of the desired pressure within a range of 15 - 150 mm Hg.
3. The HYS-Surgiflator 150P incorporates a venting valve for automatic pressure regulation, including potential reduction of overpressure.
4. The HYS-Surgiflator 150P incorporates an audible and visible overpressure alarm.
5. Use of a hydrophobic filter is required by the users manual

The utility and safety of hysteroscopic techniques using modern electronic hysteroscopic insufflators is thoroughly reported in the literature, including a discussion of the associated advantages and risks.

- A discussion of the advantages and disadvantages of the use of CO_2 gas as a distention medium during hysteroscopic procedures is presented in "Hysteroskopie", K.J. Nies, J. Hucke (1). A discussion of appropriate performance parameters for hysteroscopic insufflators as well as complications associated with hysteroscopic surgery is also included.

- A discussion of techniques, including appropriate performance parameters for hysteroscopic insufflators is provided in "Hysteroscopy: the state of the art", Hans-Joachim Lindemann, (2).

- A thorough discussion of hysteroscopy, including the history, indications, contraindications, equipment and risks is provided in "Kistner's Gynecology - Principles and Practice", Kenneth Ryan, Ross Berkowitz, Robert Barbieri (3).

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

W.O.M. GmbH
Kaiserin-Augusta-Allee 113
D-10553 Berlin
Germany.

REFERENCES

1. K.J. Nies, J. Hucke. "Hysteroskopie". Stuttgart, Georg Thieme Verlag, 1993 (Chapter IV (Van Belle) and Chapter VI (G. Göretzlehrer)).

2. Hans-Joachim Lindemann, "Hysteroscopy: the state of the art". European Journal of Obstetrics & Gynecology and Reproductive Biology 53 (1994). Pages 79-80

3. Kenneth Ryan, Ross Berkowitz, Robert Barbieri. " Kistners Gynecology - Principles and Practice". Chicago, Year Book Medical Publishers, Inc., 1990. Pages 713 - 722

Signed: M. McGrail
Michael McGrail
Agent for W.O.M. GmbH

24 Sept. 1998
Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 1999

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

Re: K983889
HYS-SURGIFLATOR 150P
(CO2 Hysteroscopic Insufflator)
Dated: October 27, 1998
Received: November 2, 1998
Regulatory Class: II
21 CFR 884.1700/Procode: 85 HIG

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 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). 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 requirements, 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

Capt. Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological 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): K983889

DEVICE NAME: HYS-Surgiflator 150P

INDICATIONS FOR USE:

The HYS-Surgiflator 150P is a hysteroscopic insufflator intended to distend the uterus by fillng the uterine cavity with a gas to facilitate viewing with a hysteroscope (21 C.F.R. § 884.1700).

(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)

Prescription Use X (Optional Format 1-2-96)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983889