K022449

510(K) SUMMARY
Hysteroscopy Pump HM4

APR 1 0 2003

I. Submitter:

W.O.M. WORLD OF MEDICINE AG
Alte Poststraße 11
96337 Ludwigsstadt
Germany

II. Device Names:

1.	Classification Name:	Hysteroscopic Insufflator and Accessories
2.	Common or Usual Name:	Hysteroscopic Insufflator, Fluid Monitoring System and Tubing Sets
3.	Proprietary Name:	Hysteroscopy Pump HM4

III. Classification:

Class II. This device is described in 21 C.F.R. § 884.1700. The product code for the device is HIG.

IV. Predicate Devices:

- **HYS-Surgimat** (K934866) manufactured by W.O.M. WORLD OF MEDICINE AG
- **Karl Storz Model 203020 20 Equimat** (K961091) distributed by Karl Storz Endoscopy-America, Inc.
- **Karl Storz Hamou Endomat** (K936231) distributed by Karl Storz Endoscopy-America, Inc.

V. Intended Use:

The Hysteroscopy Pump HM4 is a system intended to provide liquid distension of the uterus for diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.

VI. Device Description:

The Hysteroscopy Pump HM4 consists of a microprocessor controlled pump intended to distend the uterus and a monitoring unit designed to monitor the irrigation fluid losses during hysteroscopic procedures.

The pump unit functions according to the peristaltic principle. It consists of a power supply, main cable, a roller wheel, a pump head, various setting keys and display elements. The pump head is designed with two pressure sensors to

perform redundant pressure measurement. A software controlled active pressure reduction ensures the conformity of the preset nominal pressure value with the actual measured pressure. The pump unit is designed with several alarms to inform the operator in case of an overpressure. The fluid monitoring unit operates with a volume differential measurement to determine the fluid losses remained in the patient. It consists of the following components: display unit, bag holder, bag deflector, carrier plate for the pump unit, scale pole, unit stands pole, weighting unit, container holder, roller base and load controller. The deficit threshold alarm level can be selected by the operator in the range of 0 –2000 ml.

VII. Substantial Equivalence:

The Hysteroscopy Pump HM4 described in this notification is similar in design and technological characteristics to the **HYS-Surgimat** (K934866) manufactured by W.O.M. WORLD OF MEDICINE AG, the **Karl Storz Model 203020 20 Equimat** (K961091) and the **Karl Storz Hamou Endomat** (K936231) both devices distributed by Karl Storz Endoscopy-America, Inc.

In addition, both the Hysteroscopy Pump HM4 and the predicate devices are intended to provide liquid distension of the uterus for diagnostic and operative hysteroscopy, and/or to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.

The differences between the Hysteroscopy Pump HM4 and the predicate devices are minor and raise no new questions of safety and effectiveness.

Accordingly, W.O.M. WORLD OF MEDICINE AG believes that the Hysteroscopy Pump HM4 is substantially equivalent to the predicate devices currently on the market.

VIII. Performance Data:

The device will comply with the International Standard IEC 601-1 (Electrical Safety) and IEC 601-1-2 (Electromagnetic Compatibility). In addition, the device will meet the requirements of the Underwriter Laboratories standard UL 2601-1 and will bear the CE mark in accordance with the Medical Device Directive 93/42/EEC.

Signed: S Raab

Susanne Raab
Official Correspondent

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2003

W.O.M. World of Medicine AG
% Ms. Susanne Raab
Official Correspondent
320 North Columbus Street
ALEXANDRIA VA 22314

Re: K022449
Trade/Device Name: Hysteroscopy Pump HM4
Regulation Number: 21 CFR 884.1700
Regulation Name: Hysteroscopic insufflator
Regulatory Class: II
Product Code: 85 HIG
Dated: February 20, 2003
Received: February 24, 2003

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.

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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

APPLICANT: W.O.M. WORLD OF MEDICINE AG

510(K) NUMBER (if known): K022449

DEVICE NAME: Hysteroscopy Pump HM4

INDICATIONS FOR USE:

The Hysteroscopy Pump HM4 is a system intended to provide liquid distension of the uterus for diagnostic and operative hysteroscopy, and to monitor the volume differential between the irrigation fluid flowing into and out of the uterus.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)

Prescription Use ✓

David A. Ingram

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022449