FEB - 5 2004

K030837

510(k) SUMMARY
40L High Flow Insufflator F108

I. Applicant:

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

Phone number: 011 49 9263 877 0
FAX number: 011 49 9263 877 128

Establishment registration number: 8043980

Contact name: Marc Engelhardt
Contact title: Regulatory Affairs Manager
Phone number: 011 49 30 399 81 610
FAX number: 011 49 30 399 81 593
Contact e-mail address: marc.engelhardt@womcorp.com

II. Submission Correspondent:

Susanne Raab
368 St. North Asaph Street
Alexandria, VA 22314

Contact title: Regulatory Counsultant
Phone number: 703-299-0523
FAX number: 703-299-0523
Contact e-mail address: sbraab@comcast.net
soraab@aol.com

III. Date Summary was Prepared: March 13, 2003

IV. Product Information:

Classification name: Laparoscopic Insufflator

Common name: Laparoscopic Insufflator

Trade name: 40 L High Flow Insufflator F108

V. Product Classification:

Product code: 85 HIF
C.F.R. Section: 21 C.F.R. § 884.1730
Device Class : II

VI. Predicate Devices:

- **Surgiflator 40** (K001533) manufactured by W.O.M. WORLD OF MEDICINE AG

VII. Intended Use:

The 40 L High Flow Insufflator F108 is a device intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

VIII. Device Description:

The 40 L High Flow Insufflator F108 is a microprocessor controlled device designed to insufflate medical CO2 gas into peritoneal cavities during diagnostic and therapeutic laparoscopic procedures. The 40 L High Flow Insufflator F108 consists of the following main components: a housing, power supply, pressure reducers, a venting system, a fluid sensor, a gas heater, various setting keys and display elements. A continuous redundant pressure measurement controls the conformity of the actual pressure in the abdomen with the pre-set nominal pressure. The device is to be used with a specially designed heating tube and with an optional remote control.

IX. Substantial Equivalence:

The device described in this notification is similar in intended use, design and technological characteristics to the Sugiflator 40 (K001533) manufactured by W.O.M. WORLD OF MEDICINE AG.

Both the 40 L High Flow Insufflator F108 and the Surgiflator 40 (K001533) are intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it. In addition, both devices are similar in design and technical characteristics. In particular, the pressure reduction concept, the venting system and the maximum flow and pressure ranges are identical.

Unlike the predicate device, the 40 L High Flow Insufflator F108 is designed with a new software logarithm which allows for accurate flow measurements in the range of 0.1 l/min and 1 l/min and for the integration of a Low Flow Mode to ensure the safe and effective performance of the device when insufflating small abdominal cavities.

The differences between the 40 L High Flow Insufflator F108 and the predicate device are minor and raise no new questions of safety and effectiveness. Accordingly, W.O.M. WORLD OF MEDICINE AG believes that the 40 L High Flow Insufflator F108 is substantially equivalent to the predicate device.

X. **Performance Data:**

Bench tests demonstrate the safety and effectiveness of the 40 L High Flow Insufflator F108 when used in the Low Flow Mode to insufflate small abdominal cavities.

XI. **Clinical Data:**

No clinical tests were performed. A review of professional literature demonstrates the safety and effectiveness of CO2 insufflators in pediatric laparoscopy.

XII. **Voluntary Standards:**

The device complies with the International Standard IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (Electromagnetic Compatibility). In addition, the device meets the requirements of the Underwriter Laboratories Standard UL 2601-1 and bears the CE mark in accordance with the Medical Device Directive 93/42/EEC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2004

W.O.M. World of Medicine AG
% Ms. Susanne Raab
Regulatory Consultant
368 St. North Asaph Street
ALEXANDRIA VA 22314

Re: K030837
Trade/Device Name: 40 L High Flow Insufflator F108
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: 85 HIF
Dated: November 7, 2003
Received: November 7, 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 such 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

(2/4/04 fax)

Indications for Use

510(k) Number (if known): K030837

Device Name: 40L High Flow Insufflator F108

Indications For Use:

"The 40L High Flow Insufflator F108 with low flow mode is a device intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it. The low flow application of this device is indicated for pediatric use."

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030837