K973432

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

DEC - 9 1997

W.O.M. GmbH
Michael McGrail, Manager, Regulatory Affairs
Pascalstr. 11
D-10587 Berlin
Germany.

Proprietary Name: SURGIFLATOR 30
Common Name: Laparoscopic Insufflator

The Surgiflator-30 is a laparoscopic high flow insufflator intended to facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

The Surgiflator-30 described in this notification is substantially equivalent to the W.O.M. Surgiflator 20-PIM, K 955791, and the 'KSEA Thermoflator', Model 26 4320 20, by Karl Storz Endoscopy - America, Inc.

- The Surgiflator-30 incorporates the same design features as the W.O.M. Surgiflator 20-PIM. The only differences lie in the following:

  Surgiflator-30 offers an increased flow rate of max. 30 l/min. The device will also be available as a 25 l/min version.
  The Surgiflator-30 does not offer optional simultaneous pressure monitoring.

- The utility and safety of laparoscopic techniques using modern electronic high flow insufflators is thoroughly reported in the literature with the advantages and the risks well articulated.

- A comprehensive discussion of the use of insufflation methods is presented in the book "Operative Laparoscopy" (1): 9-15, by M.-A. Bruhat, 1992, which observes that Laparoscopy, along with the entire concept of minimally invasive surgery through edoscopically guided intra-abdominal surgery, has become a mainstay in gynecologic surgery. The review of instrumentation in this field includes comments on the use of modern high flow insufflators, the establishment of the pneumoperitoneum, use of instrumentation and use of CO_2-lasers.

- A detailed description of the use of different insufflator types is given in the book "Laparoscopy in gynecology, surgery and pediatrics," by H. Frongenheim. Requirements for insufflation apparatus and for the sterilization of instruments are described (2): 8-26, 39-A3

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Background information and experiences with the use of laparoscopic techniques including video-endoscopy are presented in the book "Minimal Invasive Surgery" (3): 57ff, 216-218, 291-295 by John G. Hunter, M.D. and Jonathan M. Sackier, M.D., McGraw-Hill, Inc., 3-6 and 216, 291. New technologies are discussed as well as advantages and disadvantages of minimally invasive surgery. The importance of effective, well-maintained instrumentation, i.e. insufflators and other instrumentation like light sources, television screens, and energy sources, is discussed.

REFERENCES

1. Maurice-Antoine Bruhat. "Operative Laparoscopy". New York: McGraw-Hill, 1992, 226 pages.

2. H. Frongenheim. "Laparoscopy in Gynecology, Surgery and Pediatry" Stuttgart: Georg Thieme Verlag, 1977, 214 pages.

3. John G., Hunter. "Minimally Invasive Surgery". New York: McGraw Hill, 1993, 358 pages.

Signed: 03 September 1997

Michael McGrail
Manager, Regulatory Affairs

M. McGrail

Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 1997

W.O.M. GmbH
c/o Robert P. Reznick
Hughes Hubbard & Reed
1300 I Street, N.W.
Suite 900 West
Washington, D.C. 20005-3306

Re: K973432
Surgiflator-30
Dated: September 9, 1997
Received: September 10, 1997
Regulatory Class: II
21 CFR §884.1730/Product Code: 85 HIF

Dear Mr. Reznick:

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) 594-4613. 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/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Surgiflator-30

CONFIDENTIAL

Indications For Use:

To facilitate the use of the laparoscope by filling the peritoneal cavity with gas to distend it.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K973432

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)