K090652

SEP 25 2009

510(k) SUMMARY

510(k) SUMMARY As required by Section 807.92(c))
Laparoscopic Insufflator

Applicant: HIPPOKRATEC
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Establishment registration number: not yet available

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Date Prepared: 23rd February, 2009

Product Information

Common:	Laparoscopic Insufflator
Trade Name	ALPHA DUO LAP Insufflator
Classification Names:	Laparoscopic Insufflator
C.F.R. Section:	21 C.F.R. §884.1730
Device Class	II
Product code	85 HIF

Predicate Devices

Predicate devices are produced by

Company	Property/ Device Name	510(k) No.
WISAP	Multi HI-FLO Pneu 7080	K011510
W.O.M.	40L High Flow Insufflator F108	K030837
SOPRO	SOPRO MODEL 640 LAPAROSCOPIC INSUFFLATOR	K070783

Intended Use

The intended use of the Laparoscopic Insufflator ALPHA DUO LAP is to establish and maintain a pneumoperitoneum with CO2 gas for diagnostic or operative Laparoscopy.

Device Description

The Laparoscopic Insufflator ALPHA DUO LAP with the following model variants S.2916.00 II, S.2920.00 II, S.2925.00 II, S.2930.00 II, S.2945.00 II" is a microprocessor controlled device, designed to insufflate medical CO_2 gas into peritoneal cavities during diagnostic and/or therapeutic laparoscopic procedures. The maximum flow delivery capability depends on the indexed (performance) type and ranges from 16 lpm to 45 lpm. The insufflation pressure is user adjustable between 3 and 30 mmHg. The safety features include acoustic and visual alarms for overpressure and low gas supply.

Summary of Testing

All materials used in the composition of the laparoscopic insufflator and accessories were subject to performance and physical tests to evaluate safety, effectiveness and reliability of the devices. All results were in conformance with the cited harmonized device standards. From this it follows, that this device is substantial equivalent to other SE-devices.

Information Bearing on the Safety and Effectiveness

Laparoscopic Insufflators of type ALPHA DUO LAP and accessories have the same intended use as predicate devices used in laparoscopy. They are made of the same material and produced to the same international and FDA-recognized standards. Modifications in design and dimensions do not adversely affect the safety and effectiveness of these devices.

In summary, the

- intended use
- performance attributes
- materials and
- basic design

are identical/substantially equivalent to SE devices. Then it is judged that clinical data is not needed. A review of professional literature demonstrates the safety and effectiveness of CO2 insufflators.

The results of design validation raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Hippokratec GmbH
% Mr. Stefan Preiss
Responsible Third Party Manager
TÜV SÜD America
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

SEP 25 2009

Re: K090652
Trade/Device Name: Laparoscopic Insufflator with the following device model variants: Alpha Duo Lap Insufflator (S.2916.00 II), (S.2920.00 II), (S.2925.00 II), (S.2930.00 II), and (S.2945.00 II)
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: September 8, 2009
Received: September 11, 2009

Dear Mr. Preiss:

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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090652

Device Name: **Laparoscopic Insufflator** with the following device model variants:
Alpha Duo Lap Insufflator (S.2916.00 II),
Alpha Duo Lap Insufflator (S.2920.00 II),
Alpha Duo Lap Insufflator (S.2925.00 II),
Alpha Duo Lap Insufflator (S.2930.00 II),
Alpha Duo Lap Insufflator (S.2945.00 II)

Indications for Use

The intended use of the Laparoscopic Insufflator ALPHA DUO LAP is to establish and maintain a pneumoperitoneum with CO_2 gas for diagnostic or operative Laparoscopy.

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K090652