K010783

9. Summary of Safety and Effectiveness – "510 (k) Summary"

A. Submitter Information

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DEC 13 2007

Contact Person: Steve Salesky
SOPRO
c/o ACTEON, Inc.
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054
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E-mail: steve.salesky@us.acteongroup.com

Date Prepared: March 13, 2007

B. Device Identification

Classification Name: Laparoscopic Insufflator

Common Usual Name: Laparoscopic CO_2 Insufflator

Proprietary Name: SOPRO 640 laparoscopic Insufflator

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
HI-FLO THERME PNEU 45, WISAP #7083, 7083V	WISAP GESELLSCHAFT FUR WISSENSCHAFTL. APP. BAU MB	K031014	June 27, 2003

The SOPRO 640 laparoscopic Insufflator is substantially equivalent to the predicate device by WISAP GESELLSCHAFT FUR WISSENSCHAFTL. APP. BAU MB, the HI-FLO THERME PNEU 45, WISAP #7083, 7083V (K031014) previously cleared by the FDA and currently marketed.

D. Device Description

The SOPRO 640 insufflator supplies CO_2 gas from cylinders to build up a pneumoperitoneum with CO_2 Gas for diagnostic or operative Laparoscopy with a maximum flow rate of 20, 30 or 45 liters per minute dependent on the model selected.

The insufflation pressure is user adjustable between 0 and 24 mmHg. The safety features include acoustic and visual alarms for overpressure and low gas supply.

E. Intended Use

The SOPRO 640 Laparoscopic Insufflator may only be used by qualified physicians for building up a pneumoperitoneum with CO_2 Gas for diagnostic or operative Laparoscopy.

F. Substantial Equivalence

The SOPRO 640 laparoscopic Insufflator and the predicate device by WISAP GESELLSCHAFT FUR WISSENSCHAFTL. APP. BAU MB, the HI-FLO THERME PNEU 45, WISAP #7083, 7083V (K031014) are both laparoscopic insufflators for use in diagnostic and/or operative laparoscopy by qualified physicians. Differences that exist between the devices relating to technical specifications, performances, and intended use are minor and do not affect the safety and effectiveness of the SOPRO 640 Laparoscopic Insufflator.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 3 2007

SOPRO
% Mr. Steven Salesky
Quality Manager
ACTEON North America, Inc.
124 Gaither Drive, Suite 140
MOUNT LAUREL NJ 08054

Re: K070783
Trade Name: SOPRO 640 Laparoscopic Insufflator
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Product Code: HIF
Dated: November 28, 2007
Received: November 29, 2007

Dear Mr. Salesky:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number: K070783

Device Name: **SOPRO 640 Laparoscopic Insufflator**

Indications for Use:

The SOPRO 640 Laparoscopic Insufflator may only be used by qualified physicians for building up 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 801 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 K070783