K060723

510(k) SUMMARY

Submitter:

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MAY 25 2006

Official Correspondent:

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Trade Name: 40 L High Flow Insufflator F113

Common Name: Carbon Dioxide Insufflator for Laparoscopy and Endoscopic Vessel Harvesting

Classification Name: Laparoscopic Insufflator, 21 C.F.R. 884.1730
Insufflator, Automatic Carbon Dioxide for Endoscope, 21 C.F.R. § 876.1500

Regulatory Class: II

Product Code: HIF / FCX

Predicate Devices:

- 40 L High Flow Insufflator F108 (K030837), manufactured by W.O.M. WORLD OF MEDICINE AG
- Guidant VasoView Endoscopic Vessel Harvesting System (K030512), manufactured by Guidant Corp.
- VasoView Dissection / Vessel Harvesting System (K981700), manufactured by Guidant Corp.
- Cardiovations Optical Bipolar Device (K031846), manufactured by Ethicon, Inc.

Device Description: The 40 L High Flow Insufflator F113 is a microprocessor controlled CO2 insufflator designed with a high flow application, a low flow application and a vessel harvesting application. The device incorporates the following major components and features: a housing, a world power supply,

pressure reducers, a venting system, a fluid sensor, a gas heater and various setting keys and display elements. A continuous redundant pressure measurement controls the conformity of the actual pressure in the peritoneal or extraperitoneal cavity with the pre-set nominal pressure. In addition, a software controlled active pressure reduction ensures that the preset nominal pressure value conforms to the actual pressure that is measured in the cavity. Finally, the 40 L High Flow Insufflator F113 is designed with several alarms to inform the operator in case of an overpressure. The device may be used with a heating tube and with an optional remote control.

Intended Use / Indication for Use:

The 40 L High Flow Insufflator F113 is a CO2 insufflator intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The high flow application and the low flow application of the device are each indicated for use in facilitating the use of a laparoscope by filling the peritoneal cavity with gas to distend it. The low flow application of the device is indicated for pediatric use. The vessel harvesting application of the F113 is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein and/or radial artery during endoscopic vessel harvesting procedures.

Substantial Equivalence:

The 40 L High Flow Insufflator F113 is substantially equivalent to the 40 L High Flow Insufflator F108 (K030837) manufactured by W.O.M. Specifically, the F113 and the F108 are both intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. In addition, the high flow application and low flow application of both devices are indicated for use in facilitating the use of a laparoscope by filling the peritoneal cavity with gas to distend it. The minor technological differences between the F113 and the F108 are primarily related to the implementation of a special vessel harvesting application similar to the existing low flow application for pediatric use in laparoscopy, which allows for the expansion of the indication for use of the F113 to include use of the device during endoscopic vessel harvesting procedures. Performance testing and a clinical evaluation consisting of a summary of peer reviewed literature and information on questionnaire results regarding endoscopic vessel harvesting with the aid of CO2 insufflation demonstrate that these minor technical differences and the

expansion of the device's indication for use do not raise new questions of safety or effectiveness.

Furthermore, with regards to its expanded indication for use the F113 is substantially equivalent to the Guidant VasoView Endoscopic Vessel Harvesting System (K030512), the VasoView Dissection / Vessel Harvesting System (K981700), and to the Cardiovations Optical Bipolar Device (K031846). Specifically, the F113 is substantially equivalent to the VasoView systems and to the Cardiovations Optical Bipolar Device as all three of these predicate devices are indicated to be used in conjunction with CO2 insufflation to create a cavity along the saphenous vein and/or radial artery during endoscopic vessel harvesting procedures.

Date Prepared: March 13, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 25 2006

W. O.M. World of Medicine AG
% Ms. Susanne Raab
Regulatory Affairs Consultant
1490 Cambridge Street
CANBRIDGE MA 02139

Re: K060723
Trade/Device Name: 40L High Flow Insufflator F113
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: HIF and GCJ
Dated: March 13, 2006
Received: March 17, 2006

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 (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 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 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" (21 CFR 807.97). 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) 443-6597 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

Indication for Use

510(k) Number (if known): K060723

Device Name: 40 L High Flow Insufflator F113

Indications for Use:

The 40 L High Flow Insufflator F113 is a CO2 insufflator intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The high flow application and the low flow application of the device are each indicated for use in facilitating the use of a laparoscope by filling the peritoneal cavity with gas to distend it. The low flow application of the device is indicated for pediatric use. The vessel harvesting application of the F113 is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein and/or radial artery during endoscopic vessel harvesting procedures.

Prescription Use ✓ (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 OF 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 K060723