K063367

510(k) SUMMARY

MAY 23 2007

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Trade Name:	45L CORE Insufflator F114
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 / GCJ
Predicate Devices:	1. 40 L High Flow Insufflator F113, (K060723) 2. HI-FLO Therme Pneu 45, (K031014) 3. Stryker Heated Insufflator Tube Set, (K003792) 4. Surgiflator 20, Single-Use Heatable Tube Set, (K950035)
Device Description:	The 45L CORE Insufflator F114 is a microprocessor controlled CO2 insufflator designed with a high flow application, a low flow application, a bariatric application and a vessel harvesting application. The device incorporates the following major components and features: a casing, a

world power supply, pressure reducers, a venting system, a fluid sensor, a gas heater and various setting symbols and display elements. The device is equipped with a continuous pressure measurement mode and redundant discontinuos pressure measurement mode that 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 45L CORE Insufflator F114 is designed with several alarms to inform the operator in case of an overpressure. The device is to be used with specially designed single-use tubing sets.

Intended Use / Indication for Use:

The 45L CORE Insufflator F114 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, the low flow application and the bariatric 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 45L CORE Insufflator F114 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 45L CORE Insufflator F114 (the "F114") is substantially equivalent to the 40 L High Flow Insufflator F113 (the "F113") and to HI-FLO Therme Pneu 45 (the "HI-FLO"). Specifically, both the F114 and the predicate devices F113 and HI-FLO are CO2 insufflators intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. In addition, all three devices are indicated for use in facilitating the use of a laparoscope by filling the peritoneal cavity with gas to distend it. The technical characteristics of the F114 are equivalent to those of the predicate devices. The minor technological differences between the F114 and the predicate devices are primarily related to the implementation of a special Bariatric Mode similar to the existing High Flow Mode of the F113 and identical with regard to the maximum flow performance to the High Flow Mode of the HI-FLO. In addition, the increase of the maximum gas supply pressure in the Bariatric Mode to 70 mmHg and in the High Flow Mode

to 65 mmHg and 60 mmHg (Veress Mode) does not raise new questions of safety and effectiveness. Performance testing of the bariatric mode and continuous pressure measurement in the different modes demonstrate that the minor technical differences between the F114 and the predicate devices do not raise new questions of safety or effectiveness.

In addition, the tube sets to be used in conjunction with the F114 are substantially equivalent to the Stryker Heated Insufflator Tube Set and the single-use heatable tube sets for use in conjunction with the Surgiflator 20. Both the proposed tube sets and the predicate devices are used during endosopic procedures to provide a path for the insufflation gas from the insufflation device to the patient. In addition, the technical characteristics of the proposed tube sets are equivalent to those of the predicate devices. The major difference between the proposed tube sets and the predicate devices consists of the design of the connector of the proposed tube sets, which enables the connection of the insufflation tubing and the tubing for continuous pressure measurement and the heating function in one step. The minor differences between the tube sets to be used in conjunction with the F114 and the predicate devices Stryker Heated Insufflator Tube Set and the single-use heatable tube sets for use in conjunction with the Surgiflator 20 do not raise new questions of safety and effectiveness.

Sterilization: The insufflation tube sets to be used in conjunction with the F114 will be sterilized in accordance with EN 550 "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization" method C. Residual ethylene oxide data shows that the limit of residual gas (250 ppm) will not be exceeded. In accordance with the European Standard DIN EN 14698-1 and EN1174, Part 1-3 the used sterility assurance level (SAL) to detect the quantity of bioburden was $\leq$ 10-6.

Biocompatibility: The components of insufflation tube sets that come into short term indirect contact with the patient consist of materials that are identical to those used in the predicate devices. In addition, all used materials have been well characterized chemically and physically in the published literature and have a long history of safe use in regards to biocompatibility.

Performance Data: Bench testing demonstrates the safety and effectiveness of the F114.

Date Prepared: November 3, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

W.O.M. World of Medicine AG
c/o Ms. Susanne Raab
Regulatory Consultant
1480 Cambridge Street
CAMBRIDGE MA 02139

MAY 23 2007

Re: K063367
Trade/Device Name: 45L Core Insufflator F114
Regulation Number: 21 CFR §884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: May 10, 2007
Received: May 14, 2007

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): K063367

Device Name: 45L CORE Insufflator F114

Indications for Use:

The 45L CORE Insufflator F114 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, the low flow application and the bariatric 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 F114 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 __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 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 K063367