K063546

510(k) Summary of Substantial Equivalence

JAN 10 2007

Date Prepared:	November 22, 2006
Submitter:	Lexion Medical, LLC 5000 Township Parkway St. Paul, MN 55110
Contact Person:	Duane Lloyd Research and Development Lexion Medical, LLC 5000 Township Parkway St. Paul, MN 55110 Phone: 651-204-9951 Fax: 651-635-0090 E-mail: dlloyd@lexionmedical.com
Device Name:	Insu*flow*® Device, Filter Heater/Hydrator Insufflation Gas Conditioner
Classification Name:	Laparoscopic Insufflator
Product Code:	HIF
Device Class:	II
Regulation Number:	884.1730
Intended Use:	The Lexion Medical Insu*flow*® device is an accessory to an insufflator intended to heat, humidify and filter a gas stream used for inflation during laparoscopic surgery.
Device Description:	The Insu*flow*® device is a single use device that attaches to the outlet port of an insufflator and is designed to warm and humidify the gas stream prior to insufflation into the abdominal cavity. The Insu*flow*® device consists of a disposable filter heater/humidifier tubing set and a control module that houses the control and safety circuits for the system. Gas from the insufflator flows into the Insu*flow*® device, through the in-line filter, continues along the tube to enter the Insu*flow*® device cassette that contains the heating element and humidification media, through a tube that connects via a Luer lock

connector to a trocar or insufflation needle, and finally flows into the patient's abdomen.

Predicate Device: Insu*flow*® Filter Heater/Hydrator Insufflation Gas Conditioner K970866 Decision Date: January 23, 1998

Summary of Studies: Verification testing included system performance tests designed to map the CO_2 gas temperature and humidity characteristics emitted from the Insu*flow*® under a simulated run of varying flow rates with sterile water and saline.

Electrical safety and EMC testing was performed using applicable guidelines of EN 60601-1-2, EN 55011, EN 61000-3 and EN 61000-4. The Insu*flow*® device met all specified design and performance requirements.

Biocompatibility: The Insu*flow*® device was assessed for biocompatibility according to guidelines of ISO 10993 - *Biological Evaluation of Medical Devices* and FDA G95-1 guidelines. All specified biocompatibility requirements were met.

Conclusion: Through the data and information presented, Lexion Medical LLC considers the Insu*flow*® device to be substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JAN 10 2007

Mr. Duane Lloyd
Research and Development
LEXION Medical, LLC
5000 Township Parkway
ST. PAUL MN 55110

Re: K063546
Trade/Device Name: Insu*flow*® Filter Heater/Hydrator Insufflation Gas Conditioner
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: December 28, 2006
Received: December 29, 2006

Dear Mr. Lloyd:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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 (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 (if known): K063546

Device Name: Insu*flow*® Filter Heater/Hydrator Insufflation Gas Conditioner

Indications for Use:

The Lexion Medical Insu*flow*® device is an accessory to an insufflator intended to heat, humidify and filter a gas stream used for inflation during laparoscopic surgery.

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 Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063546