SECTION 2. SUMMARY AND CERTIFICATION

JUN 24 2010

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for VasoVapor™.

SUBMITTER'S NAME: LEXION Medical LLC
ADDRESS: 5000 Township Parkway
St. Paul, MN 55110
CONTACT PERSON: Bernard (Bud) Horwath
TELEPHONE NUMBER: 651-361-8041
FAX NUMBER: 651-351-8001
DATE OF SUBMISSION: 7 May 2010

1. **Identification of device**
   Proprietary Name: VasoVapor™
   Common Name: Laparoscopic Insufflator Gas Conditioner
   Classification Status: Class II per regulations 884.1730
   Product Code: HIF

2. **Equivalent devices**
   LEXION Medical believes that VasoVapor™ is substantially equivalent to the following devices:
   Insu*flow*®, K063546
   Insu*flow*®, K090456

   VasoVapor™ is the same gas conditioner insufflator accessory device as cleared under 510(k) K063546 and K090456 and has a subset of the intended use of the predicate device cleared under 510(k) K090456.

3. **Description of the Device**
   The VasoVapor™ device is a single use device that attaches to the outlet port of an insufflator or other regulated CO_2 source and is designed to warm and humidify the CO_2 gas stream prior to insufflation into the surgical cavity. The VasoVapor™ device consists of a disposable filter heater/humidifier tubing set and a control module that houses the control and safety circuits for the system.

   Regulated CO_2 gas flows into the VasoVapor™ device, through the in-line filter, continues along the tube to enter the VasoVapor™ device cassette that contains the heating element and humidification media, through a tube that connects via a Luer lock connector to a gas entrance port or an insufflation needle/trocar and finally flows into the patient's surgical cavity.

4. **Intended use**
VasoVapor™ is a gas conditioner accessory device for use in endoscopic vessel harvesting surgical procedures, intended to heat, humidify and filter a CO_2 gas stream for insufflation of the surgical cavity.

5. **Technological characteristics, comparison to predicate device.**
Technically, the VasoVapor™ is identical to the Insu*flow*® cleared for market in 510(k) K063546 and K090456. The indications for use for the VasoVapor™ are patterned after the predicate devices, being specific to the endoscopic vessel harvesting application.

6. **Discussion of performance testing.**
Extensive performance testing has been conducted to assure that the VasoVapor™ (i.e., Insuflow®) performs in accordance with its specifications and applicable standards. Details of that testing were provided in 510(k) K063546 and K090456 are referenced in Section 5 for completeness.

7. **Conclusion**
Based on a comparison to the predicate devices, it is the conclusion of LEXION Medical that VasoVapor™ is substantially equivalent to devices already on the market being used for this application (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

JUN 24 2010

Mr. Bernard (Bud) Horwath
Regulatory Consultant
LEXION Medical LLC
5000 Township Parkway
ST PAUL MN 55110

Re: K101320
Trade Name: VasoVapor™
Regulation Number: 21 CFR §884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: May 7, 2010
Received: May 11, 2010

Dear Mr. Horwath:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

B. INDICATIONS FOR USE

510(k) Number K101320

Device Name: VasoVapor™

Indications for Use:

VasoVapor™ is a gas conditioner accessory device for use in endoscopic vessel harvesting surgical procedures, intended to heat, humidify and filter a CO_2 gas stream for insufflation of the surgical cavity.

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K101320