

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

SEP 27 2010

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for Vessel Guardian®.

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: 23 July 2010

1. Identification of device

Proprietary Name: Vessel Guardian®
Common Name: Laparoscopic Insufflator Gas Conditioner
Classification Status: Class II per regulations 884.1730
Product Code: HIF

2. Equivalent devices

LEXION Medical believes that Vessel Guardian® is substantially equivalent to the following devices:

VasoVapor™, K101320
Insuflow®, K090456

Vessel Guardian® is the same gas conditioner insufflator accessory device as cleared under 510(k) K101320 and K090456 and has the same intended use as the predicate device cleared under 510(k) K101320.

3. Description of the Device

The Vessel Guardian® device is a single use device that attaches to the outlet port of an insufflator or other regulated CO₂ source and is designed to warm and humidify the CO₂ gas stream prior to insufflation into the surgical cavity. The Vessel Guardian® 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 CO₂ gas flows into the Vessel Guardian® device, through the in-line filter, continues along the tube to enter the Vessel Guardian® 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.

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4. Intended use

Vessel Guardian® is a gas conditioner accessory device for use in endoscopic vessel harvesting surgical procedures, intended to heat, humidify and filter a CO₂ gas stream for insufflation of the surgical cavity.

5. Technological characteristics, comparison to predicate device.

Technically, the Vessel Guardian® is identical to the VasoVapor™ and Insuflow® devices cleared for market in 510(k) K101320 and K090456, respectively. The indications for use for the Vessel Guardian® 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 Vessel Guardian® (i.e., Insuflow®) performs in accordance with its specifications and applicable standards.

7. Conclusion

Based on a comparison to the predicate devices, it is the conclusion of LEXION Medical that Vessel Guardian® 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.

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

Re: K102136
Trade Name: Vessel Guardian®
Regulation Number: 21 CFR §884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: July 23, 2010
Received: July 29, 2010

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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.

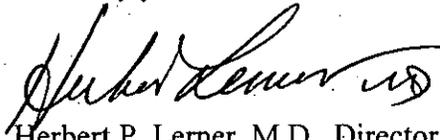
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (21 CFR 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,



Herbert P. Lerner, M.D., Director (Acting)
Division of Reproductive, Gastro-Renal
and Urological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health.

Enclosure

B. INDICATIONS FOR USE

K102136

510(k) Number K102136

Device Name: Vessel Guardian®

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Indications for Use:

Vessel Guardian® is a gas conditioner accessory device for use in endoscopic vessel harvesting surgical procedures, intended to heat, humidify and filter a CO₂ gas stream for insufflation of the surgical cavity.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and
Urological Devices
510(k) Number K102136

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