K120640

SECTION 2. SUMMARY AND CERTIFICATION

A. 510(K) SUMMARY

Summary of Safety and Effectiveness

JUL 18 2012

In accordance with 21 CFR 807.92, the following information constitutes the summary of safety and effectiveness for Insu*flow*® Synergy™ Port.

SUBMITTER'S NAME:	LEXION Medical LLC
ADDRESS:	545 Atwater Cr. St. Paul, MN 55103
CONTACT PERSON:	Bernard (Bud) Horwath
TELEPHONE NUMBER:	651-361-8041
FAX NUMBER:	651-351-8001
DATE OF SUBMISSION:	27 Feb 2012

1. **Identification of device**
   Proprietary Name: Insu*flow*® Synergy™ Port
   Common Name: Gas Conditioner Insufflator Device with integral path of entry device
   Classification Status: Class II per regulations 884.1730, Product Code: HIF
   Class II per regulations 876.1500, Product Code: GCJ

2. **Equivalent devices**
   LEXION Medical believes that Insu*flow*® Synergy™ Port is substantially equivalent to the following devices:
   SurgiQuest Trocar with integrated Insufflator, K103692
   Insu*flow*®, K090456
   EndoPath Xcel Trocar, K032676

   Insu*flow*® Synergy™ Port is a similar gas conditioner insufflator accessory device as Insu*flow*® cleared under 510(k) K090456 with an integral path of entry access port device similar to the predicate trocar device. The Insu*flow*® Synergy™ Port has the same integrated intended use as the predicate devices.

3. **Description of the Device**
   The Insu*flow*® Synergy™ Port (Dual and Single Lumen) is a gas conditioning 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 via an integral path of entry device during minimally invasive surgery. The Insu*flow*® Synergy™ Port consists of a disposable single use device with a filter, heater/humidifier, tubing set, and a path of entry access port device. A reusable control module houses the control and safety circuits for the system.

Regulated CO_2 gas flows into the Insu*flow*® Synergy™ Port, through the in-line filter, continues along the tubing to enter the path of entry access device that contains the heating element and humidification media, and through the path of entry access device lumen for delivery into the patient's surgical cavity.

The integral path of entry access device is designed and constructed similarly to the predicate trocar device with a sealed instrument access lumen. The Insu*flow*® Synergy™ Port (Dual and Single Lumen) has a dual-lumen or single-lumen path of entry access device configuration for conditioned gas delivery. Both configurations have a working channel with duckbill and tool seals for instrument entry into the surgical cavity. The single lumen device delivers conditioned insufflation gas through the working channel while the dual lumen configuration has a second outer lumen channel for conditioned gas delivery.

4. Intended use

Insu*flow*® Synergy™ Port has applications in thoracic, abdominal and gynecologic minimally invasive endoscopic surgical procedures to establish a path of entry for endoscopic instruments and to heat, humidify, filter and introduce a CO_2 gas stream for insufflation of the surgical cavity.

5. Technological characteristics, comparison to predicate device.

Technically, the Insu*flow*® Synergy™ Port gas conditioning technology is similar to the Insu*flow*® cleared for market in 510(k) K090456; the devices perform a similar gas conditioning function with minor design configuration and material changes. The Insu*flow*® Synergy™ Port path of entry access device is essentially technically equivalent to the trocar predicate; the Insu*flow*® Synergy™ Port however is configured in single and dual lumen configurations, while the predicate has only a single lumen configuration. The indications for use for the Insu*flow*® Synergy™ Port are patterned after and essentially the same as the predicate devices.

6. Discussion of performance testing.

Extensive performance testing has been conducted to assure that the Insu*flow*® Synergy™ Port (Dual and Single Lumen) performs in accordance with its specifications and applicable standards. Flow/pressure performance, gas temperature and humidity characterization, insertion/removal testing, and seal leak integrity testing were successfully completed. In addition, biocompatibility testing per ISO 10993-1 was successfully conducted.

7. Conclusion

Based on a comparison to the predicate devices and information provided, it is the conclusion of LEXION Medical that Insu*flow*® Synergy™ Port (Dual and Single Lumen) is substantially equivalent to devices already on the market being used for these applications (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

JUL 18 2012

Re: K120640
Trade/Device Name: Insuflow® Synergy Port
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF, GCJ
Dated: July 11, 2012
Received: July 12, 2012

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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120640/S2

Device Name: Insuflow® Synergy Port

Indications For Use:

Insu*flow*® Synergy™ Port has applications in thoracic, abdominal and gynecologic minimally invasive endoscopic surgical procedures to establish a path of entry for endoscopic instruments and to heat, humidify, filter and introduce a CO_2 gas stream for insufflation of the surgical cavity.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K120640