5.0 510(k) Summary

Insu*flow*® Synergy™ XL and XLR Port

Date Prepared: July 12, 2013; updated August 19, 2013

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AUG 2 2 2013

Proprietary Name
Modified Device: Insu*flow*® Synergy™ XL Port (10mm and 12mm) and Insu*flow*® Synergy™ XLR Port (10mm and 12mm with endoscopic cannula seal)

Common/Usual Name: Gas Conditioner Insufflator Device with integral path of entry device

Classification Name: Class II per regulations 884.1730, Product Code: HIF
Class II per regulations 876.1500, Product Code: GCJ

Establishment Registration Number: 2135348

Predicate Devices:
LEXION Medical believes that Insu*flow*® Synergy™ XL and XLR Port devices are substantially equivalent to the following devices:

- Insu*flow*® Synergy™ Port, K120640
- EndoPath Xcel Trocar, K032676

Description:
The Insu*flow*® Synergy™ XL and XLR Port are 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™ XL and XLR Port consist of a sterile, 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.

The technology for gas conditioning and path of entry are the same as the predicate marketed device. Regulated CO_2 gas flows into the Insu*flow*® Synergy™ XL and XLR 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 in the Insu*flow*® Synergy™ XL and XLR Port is designed and constructed similarly to the Insu*flow*® Synergy™ Port but comes in larger sizes just as the predicate EndoPath trocar device. The Insu*flow*® Synergy™ XL Port and the Insu*flow*® Synergy™ XLR Port have access devices in 10 mm and 12 mm configurations with a single-lumen working channel configuration for conditioned gas delivery. The access device has a working channel with duckbill and tool seals for instrument entry into the surgical cavity and delivers conditioned insufflation gas through the working channel. The Insu*flow*® Synergy™ XLR Port has an endoscope compatible configuration that has an additional seal at the bottom of the main cannula, which serves as a means to seal off around the endoscope, forcing all gas flow out of the peripheral gas exhaust ports. This minor change is intended to reduce fogging and improve visualization.

The obturator for the Insu*flow*® Synergy™ XL and XLR Port has a transparent optical window at the distal end, which when used with an endoscope, provides visibility of individual tissue layers during insertion.

Indications for Use:
The Insu*flow*® Synergy™ XL Port and the Insu*flow*® Synergy™ XLR Port have the same intended use as the Insu*flow*® Synergy™ Port predicate device.

Insu*flow*® Synergy™ XL Port (10mm and 12mm) and Insu*flow*® Synergy™ XLR Port (10mm and 12mm with endoscopic cannula seal) have 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.

Technological characteristics, comparison to predicate device.
The Insu*flow*® Synergy™ XL and XLR Port utilize the same gas conditioning technology, materials and path of entry access port technology as the predicate Insu*flow*® Synergy™ Port cleared under 510(k) K120640. Both devices perform a similar gas conditioning function with minor design configuration changes due to the larger trocar. The Insu*flow*® Synergy™ XL and XLR Port path of entry access devices are technically equivalent to the predicate Insu*flow*® Synergy™ Port cleared under 510(k) K120640 but are configured for 10 mm and 12 mm surgical tools where the predicate has a 5 mm configuration. The Insu*flow*® Synergy™ Port is configured in 5 mm single and dual lumen configurations, while the Insu*flow*® Synergy™ XL and XLR Port have only a single lumen configuration, similar to the EndoPath Trocar which also is available in sizes up to 12 mm. Just as with the predicate EndoPath trocar, the obturator for the Insu*flow*® Synergy™ XL and XLR Port has a transparent optical window at the distal end, which when used with an endoscope, provides visibility of individual tissue layers during insertion.

The Insu*flow*® Synergy™ XLR Port devices are endoscope compatible, utilizing a seal at the bottom of the access device cannula that prevents conditioned gas from fogging the endoscope lens.

Discussion of performance testing.
Extensive performance testing has been conducted to assure that the Insu*flow*® Synergy™ XL and XLR Port perform 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, for the Insu*flow*® Synergy™ XLR Port endoscope compatible models, a test was successfully conducted to confirm that the cannula seal configuration does reduce scope fogging and improve visualization.

Conclusion:
Based on a comparison to the predicate devices and information provided, it is the conclusion of LEXION Medical that Insu*flow*® Synergy™ XL Port and the Insu*flow*® Synergy™ XLR Port devices are 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 Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Lexion Medical, LLC
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HRG
4486 Timberline Court
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Re: K132204
Trade/Device Name: Insu*flow*® Synergy™ XL and Insu*flow*® Synergy™ XLR Port
Regulation Number: 21 CFR 870.1730
Regulatory Class: Class II
Product Code: HIF, GCJ
Dated: July 12, 2013
Received: July 23, 2013

Dear Bernard 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 contact 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. 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,

Herbert P. Lerner -S

for

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

510(k) Number (if known): K132204

Insu*flow*® Synergy™ XL Port and Insu*flow*® Synergy™ XLR Port :

Indications for Use:

Insu*flow*® Synergy™ XL Port (10mm and 12mm) and Insu*flow*® Synergy™ XLR Port (10mm and 12mm with endoscopic cannula seal) have 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 Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K132204