5.0 510(k) Summary

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

Date Prepared: January 31, 2014 (revised February 27, 2014)

Submitter: Lexion Medical, LLC
545 Atwater Circle
St. Paul, MN 55103
Telephone: 651-855-1447
Fax: 651-636-1671

Contact: Mr. Bernard Horwath
Regulatory Affairs Consultant
4486 Timberline Ct
Vadnais Heights, MN 55127
Telephone: 651- 231-1761

Proprietary Name
Modified Device: Insu*flow*® Synergy™ Port (5 mm) and Insu*flow*® Synergy™ XL Port (8 mm, 10mm and 12mm)

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 the modified Insu*flow*® Synergy™ and Synergy™ XL Port devices are substantially equivalent to the following devices:

- Insu*flow*® Synergy™ Port, K120640
- Insu*flow*® Synergy™ XL Port, K132204
- EndoPath Xcel Trocar, K032676
- SurgiQuest AirSeal, K121336

Description:
The Insu*flow*® Synergy™ and Synergy™ XL Port devices are gas conditioning devices that attach to the outlet port of an insufflator or other regulated CO_2 source and are 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™ and Synergy™ XL 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 for the modified devices are the same as the predicate Insu*flow*® Synergy™ marketed devices. Regulated CO_2 gas flows into the Insu*flow*® Synergy™ and Synergy™ XL 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 modifications included in this Special 510(k) include the following:

- Adding an 8 mm size path of entry access device to the Insu*flow*® Synergy™ family. Sizes now available are 5 mm, 8 mm, 10 mm and 12 mm.
- All access devices will be in a dual lumen configuration with a thinner inner lumen wall design that results in a smaller overall outer lumen diameter.

The integral path of entry access device in the modified Insu*flow*® Synergy™ and Synergy™ XL Port is designed and constructed similarly to the predicate Insu*flow*® Synergy™ and Synergy™ XL Port devices but an additional 8 mm access device configuration is being added, just as the predicate EndoPath and SurgiQuest trocar devices. The modified Insu*flow*® Synergy™ (5 mm) and Synergy™ XL Port devices (8 mm, 10 mm, and 12 mm) now feature a dual lumen configuration only. The predicate Insu*flow*® Synergy™ Port (5 mm) came in single and dual lumen configurations and the predicate Insu*flow*® Synergy™ XL Port (10 mm and 12 mm) had only a single-lumen working channel configuration for conditioned gas delivery and instrument entry. The modified dual lumen configuration has an inner lumen wall thickness thinner than in the predicate design which results in a smaller overall outer lumen diameter. The dual lumen access device has an inner lumen working channel with duckbill and tool seals for instrument entry into the surgical cavity and delivers conditioned insufflation gas through the outer lumen channel.

As in the predicates, the obturator for the proposed Insu*flow*® Synergy™ (5 mm) and Synergy™ XL (8 mm, 10 mm, and 12 mm) Port devices 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 modified Insu*flow*® Synergy™ Port (5 mm) and the Insu*flow*® Synergy™ XL Port (8 mm, 10 mm, and 12 mm) have the same intended use as the Insu*flow*® Synergy™ and Synergy™ XL Port predicate devices. The intended use of the modified device, as described in the labeling, has not changed as a result of the modifications.

Insu*flow*® Synergy™ Port (5 mm) and Insu*flow*® Synergy™ XL Port (8 mm, 10mm and 12mm) 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 modified Insu*flow*® Synergy™ (5 mm) and Synergy™ XL Port (8 mm, 10 mm and 12 mm) utilize the same gas conditioning technology and path of entry access port technology as the predicate Insu*flow*® Synergy™ Port (5 mm) cleared under 510(k) K120640 and the Insu*flow*® Synergy™ XL Port (10 mm and 12 mm) cleared under 510(k) K132204. All of the modified devices perform the same gas conditioning function as the predicates with minor design configuration changes. The new Insu*flow*® Synergy™ XL Port (8 mm) path of entry access device is technically equivalent to the predicate Insu*flow*® Synergy™ and Synergy™ XL Port devices but is configured for 8 mm surgical tools, just as the predicate EndoPath and SurgiQuest trocar devices. The modified Insu*flow*® Synergy™ and Synergy™ XL Port devices are configured in the dual lumen configuration while the predicate Insu*flow*® Synergy™ Port (5 mm) is configured in single and dual lumen configurations and the predicate Insu*flow*® Synergy™ XL Port (10 mm and 12 mm) devices have only a single lumen configuration. All materials in the modified Insu*flow*® Synergy™ devices are the same as the predicate Insu*flow*® Synergy™ devices.

The obturators for the modified Insu*flow*® Synergy™ and Synergy™ XL Port use the same technology and materials as the predicates with a transparent optical window at the distal end, which when used with an endoscope, provides visibility of individual tissue layers during insertion.

Discussion of performance testing.
The risk analysis and resulting performance testing have been conducted to assure that the modified Insu*flow*® Synergy™ and Insu*flow*® Synergy™ XL Port devices perform in accordance with specifications and applicable standards. All of the modified devices utilize the same exact design/parts as the predicates for gas conditioning and sealing. As a result, the existing testing for gas temperature and humidity characterization and seal leak integrity testing previously submitted applies directly to these devices. Since the lumen designs were changing, flow/pressure performance and insertion/removal testing were repeated and successfully completed for the modified Insu*flow*® Synergy™ (5 mm) and Synergy™ XL (8 mm,10 mm and 12 mm) Port dual lumen models. As a result, the risk analysis and applicable testing were successfully conducted to confirm that the Insu*flow*® Synergy™ and Synergy™ XL dual lumen configuration changes do not substantially affect their performance.

Conclusion:
Based on a comparison to the predicate devices and information provided, it is the conclusion of LEXION Medical that the modified Insu*flow*® Synergy™ Port (5 mm) and the Insu*flow*® Synergy™ XL Port (8 mm, 10 mm and 12 mm) devices are substantially equivalent to devices already on the market being used for these applications (cleared by the 510(k) process) and present 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

March 5, 2014

LEXION Medical, LLC
% Bernard Horwath
Regulatory Consultant
HRG
4486 Timberline Court
Vadnais Heights, MN 55127

Re: K140263
Trade/Device Name: Insuflow® Synergy™ and Insuflow® Synergy™ XL Port
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, GCJ
Dated: January 31, 2014
Received: February 3, 2014

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): K140263

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

Indications for Use:

Insu*flow*® Synergy™ Port (5 mm) and Insu*flow*® Synergy™ XL Port (8 mm, 10mm and 12mm) 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
2014.03.05 15:54:19 -05'00'