November 14, 2017

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

Re: K170799
Trade/Device Name: Lexion AP50/30 Insufflator with Insuflow Port
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, GCJ, OSV
Dated: October 13, 2017
Received: October 16, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170799

Device Name
Lexion AP50/30 Insufflator with Insuflow Port

Indications for Use *(Describe)*

The AP50/30 Insufflator is a CO2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The Standard/High Flow, Pediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The Pediatric operating mode is specifically indicated for pediatric laparoscopic procedures. The Vessel Harvesting operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.

The Insuflow® Port (5 mm, 8 mm, 10mm and 12mm) devices 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 CO2 gas stream for insufflation of the surgical cavity.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Lexion AP50/30 Insufflator with Insu*flow*® Port

Date Prepared: November 7, 2017

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Contact: Mr. Bernard Horwath
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Vadnais Heights, MN 55127
Telephone: 651- 231-1761

Device Name: Lexion AP50/30 Insufflator with Insu*flow*® Port

Common/Usual Name: Carbon dioxide insufflator for laparoscopic insufflation and endoscopic vessel harvesting (AP50/30), and gas conditioner path of entry device (Insuflow Port)

Classification Name/Code: Class II per regulations 884.1730, Laparoscopic Insufflator
Product Code: HIF=Insufflator, laparoscopic
Class II per regulations 884.1730, Laparoscopic Insufflator
Product Code: OSV=Insufflator, endoscopic vessel harvesting
Class II per regulations 876.1500, Endoscope and Accessories
Product Code: GCJ=Laparoscope, general and plastic surgery

Predicate Devices:
LEXION Medical believes that the AP50/30 Insufflator with Insu*flow*® Port devices is substantially equivalent to the following devices:

- Primary Predicate: Stryker/WOM 45L CORE Insufflator F114, K063367
- WOM Insufflator 50L FM134, K153513
- Lexion Insu*flow*® Synergy™ Port and Synergy™ XL Port, K140263

None of the cited predicate devices have been subject to a design-related recall.

Description:
The Lexion AP50/30 Insufflator is a microprocessor controlled CO_2 (carbon dioxide) insufflator with multiple operating modes. The insufflator instrumentation is intended for hospital use for Standard/High Flow, Pediatric, and Bariatric laparoscopic procedures used in conjunction with a laparoscope to fill and distend a peritoneal cavity with gas, and for Vessel Harvesting procedures used to create a cavity along the saphenous vein and/or the radial artery during an endoscopic vessel harvesting procedure.

The device incorporates the following major components and features: a metal housing, a

world power supply, pressure reducers, a venting system, a gas heater control and a touch screen user interface with various settings and display elements. The software operation includes system checks, user interface, setting adjustments, warning/error messages and service info. The device is equipped with a continuous pressure measurement mode that controls the conformity of the actual pressure in the peritoneal or extraperitoneal cavity with the pre-set nominal pressure. The AP50/30 Insufflator is designed with several alarms/warnings to inform the operator in case of an overpressure or other malfunctions. The device is to be used with specially designed single-use tubing sets, the Insu*flow*® Port, in order to utilize the full capabilities of continuous pressure measurement and gas heating and humidification. (The insufflator can also accept other tubing sets for gas deliver only.)

The Insu*flow*® Port (5, 8, 10, 12 mm) devices are gas conditioning/access port devices that attach to the outlet of the AP50/30 Insufflator 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*® Port consists of an ethylene oxide sterilized, disposable single use tubing set and a path of entry access port device which contains the pressure sensors, a filter, and gas heater/humidifier. The access port device materials are intended for patient contact of less than 24 hours. The Insu*flow*® Port is connected to the AP50/30 Insufflator via a plug connector cable, which controls the pressure sensing, gas heating and safety circuits for the system.

The technology for gas conditioning and path of entry for the modified port devices is the same as the predicate Insu*flow*® Synergy™ Port marketed devices. Regulated CO_2 gas from the AP50/30 Insufflator flows into the Insu*flow*® 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.

Indications for Use:
The AP50/30 Insufflator is a CO_2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The Standard/High Flow, Pediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The Pediatric operating mode is specifically indicated for pediatric laparoscopic procedures. The Vessel Harvesting operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.

The Insu*flow*® Port (5 mm, 8 mm, 10mm and 12mm) devices 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 devices.

AP50/30

The Lexion AP50/30 Insufflator is substantially equivalent to the Stryker/WOM 45L Core Insufflator (K063367) in terms of indications for use, operating mode, basic features, and custom tubing sets. Both insufflators have the same intended use and are used for the same indications. The AP50/30 Insufflator and the predicate device 45L Core Insufflator are CO_2 insufflators intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. In addition, both the proposed device and the predicate device are designed with Standard/High Flow, Pediatric and Bariatric operating modes that are indicated to fill and distend a peritoneal cavity with

gas during a laparoscopic procedure. Both insufflators also incorporate a Vessel Harvesting operating mode that is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.

The AP50/30 Insufflator and the predicate 45L Core Insufflator use the same basic operating principles and incorporate the same basic design technology. Both are microprocessor controlled CO_2 insufflators that consist of similar major components and incorporate the same type of features, including continuous pressure measurement. In addition, both the proposed device and the predicate device 45L Core Insufflator are to be used with specially designed sterile, single-use tube sets. The following table provides a comparison of key performance specs for the two insufflators.

Comparison Table: Key Performance Specs

Key Performance Specs	AP50/30 Insufflator	45L CORE Insufflator	Comparison
Insufflator Indications for Use	The AP50/30 Insufflator is a CO_2 insufflator intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The Standard/High Flow, Pediatric and Bariatric operating modes of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The Pediatric operating mode is specifically indicated for pediatric laparoscopic procedures. The Vessel Harvesting operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery.	The 45L CORE Insufflator F114 is a C02 insufflator intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. The high flow application, the low flow application and the bariatric application of the device are each indicated for use in facilitating the use of a laparoscope by filling the peritoneal cavity with gas to distend it. The low flow application of the device is indicated for pediatric use. The vessel harvesting application of the 45L CORE Insufflator F 114 is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein and/or radial artery during endoscopic vessel harvesting procedures.	Different; the differences between the subject and predicate indications statements are minor and do not alter the intended use
Operating Modes	Standard/High Flow, Pediatric, Bariatric and Vessel Harvesting	Standard/High Flow, Pediatric, Bariatric and Vessel Harvesting	Same
Max Gas Flow	20 lpm (Pediatric) 45 lpm (High Flow) 50 lpm (Bariatric) 10 lpm (Vessel Harvest)	20 lpm (Pediatric) 40 lpm (High Flow) 45 lpm (Bariatric) 10 lpm (Vessel Harvest)	Different; the flow rate of the subject device in bariatric and high flow is higher than the predicate; these differences do not raise different

Key Performance Specs	AP50/30 Insufflator	45L CORE Insufflator	Comparison
			questions of safety and effectiveness
Pressure Range	1-20mmHg (Pediatric/Vessel Harvest) 1-30mmHg (High Flow/Bariatric)	1-20mmHg (Pediatric/Vessel Harvest) 1-30mmHg (High Flow/Bariatric)	Same
Intra-abdominal Max Pressure	30 mmHg (High Flow/Bariatric) 20 mmHg (Pediatric/Vessel Harvest)	30 mmHg (High Flow/Bariatric) 20 mmHg (Pediatric/Vessel Harvest)	Same
Maximum Supply Pressure	65 mm Hg in Bariatric, High Flow, Pediatric and Vessel Harvest modes and 60 mm Hg in Veress mode	70 mm Hg for Bariatric mode, 65 mm Hg for High Flow mode and 60 mm Hg in Veress mode	Different; the subject device maximum supply pressure is lower for bariatric setting. This difference does not raise different questions of safety and effectiveness.
Adjustable Values	Pressure: 1-30 mmHg Flow: 1-50 lpm	Pressure: 1-30 mmHg Flow: 1-45 lpm	Different; the flow rate of the subject device is higher than the predicate; this differences does not raise different questions of safety and effectiveness
Pneumo Pressure Control	Constantly held based upon pressure sensors in Insu*flow* Port or standard insufflation using pressure sensing in the insufflator	Constantly held based upon real time pressure sensing tube or standard insufflation using pressure sensing in the insufflator	Same
User Interface	Touch screen	Touch screen	Same
Power	100-240 V	100-240 V	Same
Touch Screen Menus (Menu Options)	Configuration Menus: - First Nominal Pressure 15mmHg (high flow) 15mmHg (bariatric) 10mmHg (vessel harvesting) 8mmHg (pediatric) - Venting Valve Status with Veress insufflation on or off, Venting system on or off - Venting Pressure Limit: set at	Configuration Menus: - First Nominal Pressure 15mmHg (high flow) 15mmHg (bariatric) 10mmHg (vessel harvesting) 8mmHg (pediatric) - Venting Valve Status with Veress insufflation on or off, Venting system on or off - Venting Pressure Limit: set	Different; Pressure limits for venting are preset in the subject device, while they can be adjusted in the predicate. Gas flow rates differ to reflect differences in flow range. These differences do not raise different

Key Performance Specs	AP50/30 Insufflator	45L CORE Insufflator	Comparison
	3mmHg (cannot be changed) - Venting Response time: set at 3 sec (cannot be changed) - Gas Supply: House or Bottle - Alarm Volume: set between Level 1-3 - Gas Flow Rates: Quick set rate 1-3 3, 20, 45 LPM (high flow) 3, 25, 50 LPM (bariatric) 1.0, 4.0, 10.0 LPM (vessel harvesting) 0.1 LPM (pediatric) - Maximum Nominal Pressure: setting range 5-30 mmHg for bariatric and high flow setting range of 5-20 mmHg for vessel harvesting and pediatric - Flow Safety Limit: Limit On or Off - Warning Signal Occlusion: Signal On or Off - Language: English, Spanish	between 2-5 mmHg - Venting Response time: between 2-5 sec - Gas Supply: House or Bottle - Alarm Volume: set between Level 1-3 - Gas Flow Rates: Quick set rate 1-3 3, 20, 40 LPM (high flow) 5, 25, 45 LPM (bariatric) 1.0, 4.0, 10.0 LPM (vessel harvesting) 0.1 LPM (pediatric) - Maximum Nominal Pressure: setting range 5-30 mmHg for bariatric and high flow setting range of 5-20 mmHg for vessel harvesting and pediatric - Flow Safety Limit: Limit On or Off - Warning Signal Occlusion: Signal On or Off - Language: English, Spanish	questions of safety and effectiveness.
Error Warnings	Check gas supply, low supply gas pressure, overpressure, venting system active, overpressure/venting system active, occlusion, contamination, contamination/call for service, gas heater/call for service, error message/call for service, device temperature error/turn off device, venting valve non-functioning, continuous pressure sensing deactivated/call for service, flow safety limit, safety limit, valve non-functioning/call for service	Check gas supply, low supply gas pressure, overpressure, venting system active, overpressure/venting system active, occlusion, contamination, contamination/call for service, gas heating defective/call for service, gas temperature >42C, error message/call for service, device temperature error/turn off device, venting valve defective, RTP defective	Different; the minor differences do not raise different questions of safety and effectiveness
Gas Conditioning	Heat and humidify	Heat	Different; the subject device includes humidification with the use of the Insuflow port; this

Key Performance Specs	AP50/30 Insufflator	45L CORE Insufflator	Comparison
			difference does not raise different questions of safety and effectiveness
Tubing Sets	Custom, sterile, single use Insu*flow* Port	Custom, sterile, single use	Same

The technical differences between the proposed Lexion AP50/30 Insufflator and the predicate Stryker/WOM 45L Core Insufflator include the following:

- The housing of the proposed AP50/30 Insufflator is slightly smaller in dimensions and lighter in weight.
- The maximum flow rate in the Bariatric operating mode has been increased from 45 l/min to 50 l/min in the AP50/30 Insufflator.
- Continuous pressure measurement is provided by sensors in the Insu*flow*® Port while the predicate device 45L Core Insufflator utilizes a real time pressure sensing tube.
- The AP50/30 Insufflator provides heated, humidified CO_2 via the Insu*flow*® Port while the 45L Core Insufflator provides just heated CO_2.
- There are minor differences in configuration menus and settings, highlighted above.

The differences in the technological characteristics of the proposed AP50/30 Insufflator and the predicate 45L Core Insufflator do not raise different questions of safety and effectiveness. The the maximum flow rate to 50 l/min for the AP50/30 Insufflator is identical to the secondary predicate WOM Insufflator 50L FM134 (K153513).

Insuflow® Port

The modified Insu*flow*® Port (5 mm, 8 mm, 10 mm, and 12 mm) devices 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 AP50/30 modifications.

The modified Insu*flow*® Port (5 mm, 8 mm, 10 mm and 12 mm) devices utilize the same gas conditioning technology and path of entry access port technology as the predicate Insu*flow*® Synergy™ Port (5 mm) and the Insu*flow*® Synergy™ XL Port (8 mm, 10 mm and 12 mm) cleared under 510(k) K140263. All of the modified devices have the same port configuration, design and materials as the predicates. All of the Insu*flow*® Ports perform the same gas heating/humidification conditioning function as the predicates with minor design changes to accommodate the pressure sensors added to the circuitry. The lumen configurations, dimensions and materials of the Insu*flow*® Port path of entry access device are equivalent to the predicate Insu*flow*® Synergy™ and Synergy™ XL Port devices.

Discussion of performance testing.

A risk analysis and resulting performance testing have been conducted to assure that the AP50/30 Insufflator with the Insu*flow*® Port devices perform in accordance with specifications and applicable

standards. Design verification testing of the AP50/30 Insufflator demonstrates that the device performs as intended, and that performance of the device is comparable to that of the predicate.

Electrical safety and electromagnetic compatibility testing was successfully performed by independent laboratories in accordance with the following standards:

- IEC 60601-1:2014 Ed 3- Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2:2014 – Medical Electrical Equipment – Part 1 -2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

The software used in the AP50/30 Insufflator was determined to have a major level of concern, and was developed and successfully validated in accordance with the FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued May 11, 2005.

Comparative bench testing was performed to demonstrate that the performance of the AP50/30 Insufflator is substantially equivalent to that of the predicate device Stryker/WOM 45L Core Insufflator. The comparative bench test included the following tests: set pressure, compensation of small and large leakages, overpressure, and pressure measurement/control. The test results demonstrate that the performance of the proposed AP50/30 device related to reaching the set pressure, compensation of small and large leakages, pressure measurement/control and overpressure are comparable to the performance of the predicate device 45L Core Insufflator.

For the Insu*flow*® Port devices, the subject devices utilize the same design and materials as the predicate for gas conditioning, port access and sealing. The only difference is the addition of the pressure sensors on the subject device circuitry. Per FDA's biocompatibility guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," issued June 16, 2016, testing of the Insuflow device as an external communicating device with contact duration of less than 24 hours was conducted and included cytotoxicity, irritation, sensitization potential, and acute systemic toxicity per ISO 10993-5:2009(R)2014, ISO 10993-10:2010/(R)2014, and ISO 10993-11:2006/(R)2010 respectively. Analysis and testing of the sensor materials exposed to the gas flow demonstrated acceptable biocompatibility per ISO 10993-1. Because there was no change in device dimensions, the existing test data for insertion/removal testing, seal leak integrity testing and ETO sterilization previously provided in the predicate submission can be leveraged to support the safety and effectiveness of the subject device. Since the AP50/30 Insufflator now controls the heating and humidification of the Insu*flow*® Port device, gas temperature and humidity characterization and flow/pressure performance testing was successfully conducted to assure compliance to specification.

Conclusion:

The subject and predicate devices have the same intended use. As identified above, there are several technological differences between the subject and predicate devices. None of these differences alter the intended use of the subject device from that of the predicate, or raise different questions of safety and effectiveness. Performance testing conducted on the subject device demonstrate that the subject device is as safe and effective as the predicate. Therefore, the AP50/30 Insufflator with Insu*flow*® Port is substantially equivalent to the predicate devices.