DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 15, 2017

W.O.M. WORLD OF MEDICINE GmbH
% Susanne Raab
Regulatory Consultant
Susanne Raab
1480 Cambridge Street
Cambridge, MA 02139

Re: K170784
Trade/Device Name: PNEUMOCLEAR™
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, OSV
Dated: February 10, 2017
Received: March 15, 2017

Dear Susanne Raab:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Benjamin R. Fisher -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170784

Device Name
PNEUMOCLEAR™

Indications for Use *(Describe)*

The device PNEUMOCLEAR™ 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/Bariatric, Pediatric and Advanced Flow operating mode of the device are indicated to fill and distend a peritoneal cavity with gas during a laparoscopic procedure. The Pediatric operating mode is indicated for pediatric laparoscopic procedures. The Vessel Harvest operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery. The TAMIS operating mode is indicated to fill and distend the rectum and colon using CO_2 gas during trans anal minimal invasive surgery.

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.

PNEUMOCLEAR™
510(k) Premarket Notification

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

General Information:

Submitter: W.O.M. WORLD OF MEDICINE GmbH
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Date Prepared: May 12, 2017

Proposed Device:

Trade Name: PNEUMOCLEAR™
Common Name: Carbon Dioxide Insufflator for Laparoscopy and Vessel Harvesting
Classification Name: Insufflator, Laparoscopic
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, OSV

Predicate Devices:

Primary Predicate:

Trade Name: Insufflator 50L FM134
510(k) Number: K153513
Applicant: W.O.M. WORLD OF MEDICINE GmbH
Regulation Number: 21 CFR 884.1730
Regulatory Class: II
Product Code: HIF, OSV

PNEUMOCLEAR™
510(k) Premarket Notification

Secondary Predicates

Trade Name:	SurgiQuest AirSeal iFS System
510(k) Number:	K143404
Applicant:	SurgiQuest, Inc.
Regulation Number:	21 CFR 884.1730
Regulatory Class:	II
Product Code:	HIF, GCJ

Reference Devices:

Trade Name:	Olympus High Flow Insufflation Unit UHI-4
510(k) Number:	K122180
Applicant:	Olympus Medical Systems, Corp.
Regulation Number:	21 CFR 884.1730 and 21 CFR 876.1500
Regulatory Class:	II
Product Code:	FCX, HIF and OSV

Trade Name:	Insuflow
510(k) Number:	K090456
Applicant:	LEXION Medical LLC
Regulation Number:	21 CFR 884.1730
Regulatory Class:	II
Product Code:	HIF

Device Description:

The PNEUMOCLEAR™ is a microprocessor controlled CO_2 insufflator that consists of the following major components and features: (1) a casing, (2) a world power supply, (3) pressure reducers, (4) pressure sensors, (4) venting systems, (5) various safety valves, (6) a suction pump, (7) a fluid sensor and (8) a software controlled graphical user interface (GUI) touch screen with various setting keys and display elements. The proposed device offers six operating modes (*i.e.* Standard, High Flow/Bariatric, Pediatric, Advanced Flow, Vessel Harvest, and TAMIS. The PNEUMOCLEAR™is not intended to enter the sterile field, and cannot be sterilized. It is to be used with specially designed single-use insufflation tube sets that are delivered sterile. Specifically, five different tube sets may be used with the proposed device: (1) insufflation tube set with integrated filter, (2) insufflation tube set with integrated filter and heating wire; (3) insufflation tube set with integrated filter, heating wire and humidification media; (4) insufflation and smoke evacuation tube set with integrated filter, heating wire, and humidification media; and insufflation and smoke evacuation tube set with integrated filter. When used with a smoke evacuation tube set the PNEUMOCLEAR™ allows for removal and filtration of CO_2 and surgical smoke from the abdomen, rectum or colon during laparoscopic

and transanal minimally invasive procedures and at the end of a procedure.

Intended Use / Indication for Use:

The device PNEUMOCLEAR™ 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/Bariatric, Pediatric and Advanced Flow 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 indicated for pediatric laparoscopic procedures. The Vessel Harvest operating mode is indicated for use during endoscopic vessel harvesting procedures to create a cavity along the saphenous vein or radial artery. The TAMIS operating mode is indicated to fill and distend the rectum and colon using CO_2 gas during trans anal minimally invasive surgery.

Substantial Equivalence and Comparison of Technological Characteristics:

The PNEUMOCLEAR™ is substantially equivalent to the predicate devices Insufflator 50L FM134 (K153513) and SurgiQuest AirSeal iFS System (K143404). The PNEUMOCLEAR™ has features similar to those seen in the reference devices Olympus High Flow Insufflation Unit UHI-4 (K122180) and Insuflow (K090456).

The proposed device, PNEUMOCLEAR™, and the predicate devices, Insufflator 50L FM134 and SurgiQuest AirSeal iFS System, as well as the reference device, Olympus High Flow Insufflation Unit UHI-4, are all CO_2 insufflators intended for use during diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas. In addition, the PNEUMOCLEAR™ is used for the same or similar indications as the primary predicate device Insufflator 50L FM134, *i.e.* Standard, Bariatric, Pediatric, Vessel Harvest. With regards to the TAMIS indication the PNEUMOCLEAR™ is substantially equivalent to the secondary predicate device, SurgiQuest AirSeal iFS System, that is also indicated to fill and distend the rectum and colon using CO_2 gas during trans anal minimally invasive surgery.

Furthermore, the PNEUMOCLEAR™ and the primary predicate device, Insufflator 50L FM134, use the same basic operating principles and incorporate the same basic design. Both the proposed device PNEUMOCLEAR™ and the primary predicate device, Insufflator 50L FM134, are microprocessor controlled CO_2 insufflators that consist of the same major components and incorporate the same major features except for the addition of a suction pump to provide for smoke evacuation in the proposed device. In addition, both the proposed device and the primary predicate device are to be used with specially designed sterile, single-use insufflation tube sets with integrated filter and optional heating function.

The differences in the technological characteristics between the proposed device, PNEUMOCLEAR™, and the primary predicate device, Insufflator 50L FM134, do not raise different questions of safety or effectiveness.

Specifically, with regards to the Advanced Flow Operating Mode, the proposed device is substantially equivalent to the Bariatric Operating Mode of the primary predicate device, Insufflator 50L FM134. The main technological differences between the Advanced Flow Operating Mode of the proposed device and the Bariatric Operating Mode of the primary predicate device, Insufflator 50L FM134, consist of an increased maximum gas supply pressure and a special "Intelligent Steady Insufflation" algorithm (Steady Control Feature) that is automatically activated if a large leakage is detected that cannot be compensated with the "conventional intermitted insufflation cycles" of the proposed device. With the Steady Control Feature of the Advanced Flow Operating Mode active, the length of the insufflation cycles are extended compared to the "conventional intermitted insufflation cycles". The Advanced Flow Operating Mode of the proposed device is designed with two safety features to prevent a rise in abdominal pressure above the set value during the extended insufflation cycles of the Steady Control Feature: (1) the plausibility check flow; and (2) the plausibility check pressure. Both the plausibility check flow and pressure are performed permanently while the Steady Control Feature is active, to detect any change in the abdominal pressure and if required to deactivated the Steady Control Feature during operation of the Advanced Flow Operating Mode.

In addition, with regards to the TAMIS Operating Mode, the proposed device is substantially equivalent to the secondary predicate device, SurgiQuest AirSeal iFS System. In addition, the smoke evacuation function and the smoke evacuation tube sets of the proposed device can be found in the reference device, Olympus High Flow Insufflation Unit UHI-4, and secondary predicate device, SurgiQuest AirSeal iFS System. Finally, with regards to the PNEUMOCLEAR™ tube sets with integrated humidification media, these components can be found in the reference device, Insuflow.

Performance Data:

Electrical Safety and Electromagnetic Compatibility Testing:

Electrical safety and electromagnetic compatibility testing was performed by independent laboratories and the test results demonstrate that the proposed device conforms to the below standards:

- IEC 60601-1 2005/(R)2012 and A1:2012, C1:2009/(R)2012 andA2:2010/(R)2012 (consolidated text); and

- IEC 60601-1-2 Third Edition: 2007-03.

Software:

The software was considered as major level of concern in accordance with the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Software verification and validation testing of the PNEUMOCLEAR™ demonstrates that the device performs as intended. It was developed, tested and verified in accordance with the above FDA guidance document and in accordance with the following standard:

- IEC 62304 First Edition 2006-05.

Biocompatibility Testing:

Biocompatibility testing was performed on the insufflation tube sets of the proposed device PNEOMOCLEAR™ in accordance with:

- AAMI/ANSI/ISO 10993-1 Fourth Edition 2009-10-15;
- ISO 10993-5: 2009 (R) 2014;
- ISO 10993-10 Third Edition 2010-08-01; and
- ISO 10993-11 Second Edition 2006-08-15.

Sterilization and Package Testing:

ETO sterilization validation for the sterile single use tube sets was performed in accordance with the below standards:

- ISO 11135-1 Second Edition 2014;
- ISO 14937 Second Edition 2009-10-15;
- ISO 10993-7 Second Edition 2008-10-15; and
- AAMI TIR 28 2009/(R)2013.

Residual ethylene oxide (EO) and ethylene chlorohydrin (ECH) data shows that the limit of EO < 4 mg and ECH < 5 mg after 4 days of aeration (gas release) that remains on the tube set will not be exceeded. A sterility assurance level (SAL) $\leq 10^{-6}$ is achieved. Package and product integrity of the tube sets were tested in accordance with the following standards:

- ISO 11607-1 First Edition 2006-04-15; and
- ASTM-F-1980: 2002.

Bench Testing:

Finally, bench testing was performed to demonstrate that the performance of the proposed device, PNEUMOCLELAR™, is substantially equivalent to that of the predicate devices:

1. Comparative Bench Testing comparing the pressure regulation of the PNEUMOCLEAR™ High Flow/Bariatric Operating Mode with the performance in the Standard Operating Mode of the primary predicate device, Insufflator 50L FM134;

2. Comparative Bench Testing comparing the pressure regulation of the PNEUMOCLEAR™ Flow/Bariatric Operating Mode with the performance in the Bariatric Operating Mode of the primary predicate device, Insufflator 50L FM134;

3. Comparative Bench Testing, comparing the Advanced Flow Operating Mode of the PNEUMOCLEAR™ with the Bariatric Operating Mode of the INSUFFLATOR 50L FM134;

4. Bench Testing demonstrating the safety and effectiveness of the Steady Control Feature while in the Advanced Flow Operating Mode;

5. Comparative Bench Testing comparing the Advanced Flow Operating Mode of the PNEUMOCLEAR™ with the Bariatric Operating Mode of the INSUFFLATOR 50L FM134 in terms of large leakage compensation and maintenance of abdominal pressure with the Steady Control Feature active.

6. Comparative Bench Testing comparing the pressure regulation performance of the PNEUMOCLEAR™ TAMIS Operating Mode with the secondary predicate device, SurgiQuest AirSeal iFS System, with and without the activation of the smoke evacuation function;

7. Bench Testing demonstrating the effectiveness of the Stryker SDC3 HD Information Management System in controlling the PNEUMOCLEAR™ and to remotely display device settings and warning messages;

8. Bench Testing demonstrating the effectiveness of the radio frequency identification (RFID) transponder technology tube set recognition function;

9. Comparative Bench Testing comparing the smoke evacuation function of the PNEUMOCLEAR™ with the smoke evacuation function of the reference device, Olympus High Flow Insufflation Unit UHI-4;

10. Bench Testing demonstrating the safety and effectiveness of the desufflation function of the PNEUMOCLEAR™;

11. Comparative bench testing comparing the performance of the PNEUMOCLEAR™ insufflation tube set with integrated filter and heating wire ST296 with the insufflation tube set with integrated filter and heating wire ST260 of the primary predicate device, FM134, in terms of safety and effectiveness; and

12. Comparative bench testing was performed comparing the performance of the PNEUMOCLEAR™ insufflation tube set with integrated filter, heating wire and humidification material ST297 with the reference device, Insuflow.

Conclusion:

The PNEOMOCLEAR™ is substantially equivalent to the predicate devices: Insufflator 50L FM134, SurgiQuest AirSeal iFS System.