July 29, 2020

W.O.M. WORLD OF MEDICINE GmbH
Soeren Markworth
Head of Regulatory Affairs
Salzufer 8
Berlin, Berlin 10587
Germany

Re: K201361
Trade/Device Name: PNEUMOCLEAR™
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, OSV
Dated: May 22, 2020
Received: May 22, 2020

Dear Soeren Markworth:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason R. Roberts, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201361

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 CO_2 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 transanal minimally 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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: July 24, 2020

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 Device:

Trade Name: PNEUMOCLEAR™
510(k) Number: K170784
Applicant: W.O.M. WORLD OF MEDICINE GmbH
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II

PNEUMOCLEAR™
510(k) Premarket Notification

Product Code: HIF, OSV

The PNEUMOCLEAR™ has not been subject to a design related recall.

Device Description:

The PNEUMOCLEAR™ is a microprocessor controlled device that consists of the following major components and features: a casing, a world power supply, pressure reducers, pressure sensors, venting systems, various safety valves, a suction pump, a fluid sensor and a software controlled graphical user interface (GUI) touch screen with various setting keys and display elements. The proposed device offers six operating modes: 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 one of the following specially designed, single-use, sterile insufflation tube sets: (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 (5) insufflation and smoke evacuation tube set with integrated filter. When a smoke evacuation tube set is connected, 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 CO_2 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 transanal minimally invasive surgery.

Comparison of Technological Characteristics:

The PNEUMOCLEAR™ that is the subject of this 510(k) is substantially equivalent to its predicate, predecessor K170784 PNEUMOCLEAR™. This is a catch-up 510(k) submission intended to update the PNEUMOCLEAR™ record at FDA with the changes that have been implemented for the device. As such, the intended use and indications remain identical to those for the cleared device. Further, the

implemented changes were primarily to tweak the optional features based on user feedback or internal, routine, developmental updates. These are captured in the comparison table below.

Substantial Equivalence Comparison Table

	Cleared Device: **PNEUMOCLEAR™** **(K170784)**	**Subject Device:** **PNEUMOCLEAR™** **(this submission)**
Manufacturer	W.O.M.World of Medicine GmbH	Identical
Regulation Number	884.1730	Identical
Regulation Name	Laparoscopic Insufflator	Identical
Procodes	HIF, OSV	Identical
Indications 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 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.	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 CO_2 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 minimal invasive surgery.

PNEUMOCLEAR™
510(k) Premarket Notification

Substantial Equivalence Comparison Table		
	Cleared Device: **PNEUMOCLEAR™** **(K170784)**	**Subject Device:** **PNEUMOCLEAR™** **(this submission)**
Target Population	Patients undergoing the procedures indicated for the device.	Identical
Target Users	For physicians and trained hospital staff.	Identical
Power source	Line powered	Identical
Mechanism of Action	Insufflation of the target area, which is monitored and maintained by a microprocessor-controlled, electronic-mechanical system	Identical
Maximum Flow	50 l/min	Identical
Maximum Pressure	30 mmHg	Identical
Heating Option	Yes	Identical
Humidification Option	Yes	Identical
Smoke Evacuation Option	Yes	Identical
Tube Sets		

Substantial Equivalence Comparison Table		
	Cleared Device: **PNEUMOCLEAR™** **(K170784)**	**Subject Device:** **PNEUMOCLEAR™** **(this submission)**
Model ST295	Insufflation tube set with integrated filter	Identical
Model ST296	Insufflation tube set with integrated filter and heating wire	Identical Packaging change to address a shipping issue.
Model ST297	Insufflation tube set with integrated filter, heating wire and humidification	Implemented a manufacturing change to better seal a component.
Model ST298	Insufflation and smoke evacuation tube set with integrated filter, heating wire and humidification	• Implemented a manufacturing change to better seal a component. • Implemented a design change to a gas line.
Model ST299	Insufflation and smoke evacuation tube set with integrated filter	Implemented a design change to a gas line.
Sterilization Process	EO	Identical
Materials	MABS, PVC, Hydrophobic Glass Fiber, Polyolefin, Silicone, FEP, Polyester, Nylon.	Additional Terlux 2802 and fiber materials for the design change to a gas line.
Single-Use	Yes	Identical
Shelf-life	3 years	Identical
Software	Version 1.0.27	Version 1.0.34

PNEUMOCLEAR™
510(k) Premarket Notification

The differences between the two versions of PNEUMOCLEAR™ do not raise different questions of safety and effectiveness and have been confirmed through testing.

Performance Data:

The changes implemented for the PNEUMOCLEAR™ were confirmed using the same guidance/recognized standards that were used for the cleared device. These include:

- **Electrical Safety and Electromagnetic Compatibility**
  - AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
  - IEC 60601-1-2 Edition 4.0 2014-02

- **Packaging and Shelf-Life Testing**

  The effectiveness of the tube set barrier provided by the modified packaging was confirmed using the following transportation, packaging and shelf-life standards:
  - ASTM D642 (2015)
  - ASTM D999 (2008)
  - ASTM D4169 (2016)
  - ASTM D4728 (2006)
  - ASTM D5276 (1998)
  - ASTM D6344 (2004)
  - ASTM F88 (2015)
  - ASTM F1886 (2016)
  - ASTM F1929 (2015)
  - ASTM F1980 (2016)
  - ASTM F2096 (2011)
  - ISO 11607-1 First Edition 2006-04-15
  - ISO 2233 (2001)

- **Software/Bench Testing**

  W.O.M. developed and verified the software in accordance with a major level of concern described in the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and following the IEC 62304 Edition 1.1 2015-06 standard.

  The sensor sealing process for tube sets ST297 and ST298 was modified and confirmed through submerged testing. The gas line for the ST297 and ST298 tube sets was modified to improve the surgical smoke evacuation and verified through simulated use testing.

The complete Version 1.0.34 software and all other changes were bench-tested to confirm that they met their requirements before implementation.

Conclusion:

The provided performance testing supports a substantial equivalence determination. The subject PNEUMOCLEAR™ is substantially equivalent to its predicate, predecessor K170784 PNEUMOCLEAR™.