



March 28, 2019

ConMed Corporation  
Ms. Lisa Anderson  
Manager, Regulatory Affairs  
525 French Road  
Utica, New York 13502

Re: K190303

Trade/Device Name: AirSeal iFS System  
Regulation Number: 21 CFR 884.1730  
Regulation Name: Laparoscopic Insufflator  
Regulatory Class: Class II  
Product Code: HIF, GCJ  
Dated: February 8, 2019  
Received: February 12, 2019

Dear Ms. Anderson:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen

-S

Date: 2019.03.28 09:12:52 -04'00' for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K190303

Device Name

AirSeal IFS System

Indications for Use (Describe)

The ConMed AirSeal® iFS System is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas, to create and maintain a gas-sealed obstruction-free path of entry for endoscopic instruments, and to evacuate surgical smoke.

It is indicated for use in abdominal, thoracic, and pediatric ( $\geq 20\text{kg}$ ) procedures where insufflation is desired to facilitate the use of various thoracoscopic and laparoscopic instruments by filling the abdominal or thoracic cavity with gas to distend it, by creating and maintaining a gas sealed obstruction-free instrument path and by evacuating surgical smoke. This instrument can also be used to insufflate the rectum and colon to facilitate endoscopic observation, diagnosis, and treatment. The trocar of the AirSeal® iFS System is indicated for use with or without visualization.

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 of Safety and Effectiveness

### CONMED AirSeal iFS System

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) number K190303 as of March 27, 2019.

#### A. Submitter

ConMed Corporation  
525 French Road  
Utica, NY 13502  
Establishment Registration: 1320894

#### B. Company Contact

Lisa Anderson  
Manager, Regulatory Affairs  
T: (941) 713-2035

#### C. Device Name

Proprietary Name:	AirSeal iFS
Common Name:	Disposable Endoscopic Trocar and Cannula Carbon Dioxide Insufflator for Laparoscopy Endoscopic Insufflator
Classification Name:	Laparoscopic Insufflator Endoscope and Accessories
Regulation Number:	884.1730, 876.1500
Product Code:	HIF, GCJ
Regulatory Class:	II
Panel:	General and Plastic Surgery

#### D. Predicate Device

Primary Device Name:	WOM 45L CORE Insufflator, Model F114
Company Name:	W.O.M. World of Medicine GmbH
510(k):	K063367 (Marketed by Stryker as the PneumoSure High Flow Insufflator)

Secondary Device Name:	AirSeal iFS System
Company Name:	CONMED Corporation
510(k):	K172516

#### E. Device Description

The ConMed AirSeal iFS System consists of the following major components: (1) a trocar, (2) a cannula, (3) tube sets, and (4) a microprocessor-controlled insufflation, recirculation and filtration unit. The cannula, trocar and tube sets are sterile, single-use products. The AirSeal iFS System is an active medical device, nonsterile and reusable and is intended to insufflate a body cavity. The AirSeal iFS System is designed to function in one of three (3)

separate modes of operation: (a) Insufflation Mode; (b) AirSeal Mode (Adult and Pediatric); or (c) Smoke Evacuation Mode.

### **Intended Use / Indications for Use**

The ConMed AirSeal® iFS System is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas, to create and maintain a gas-sealed obstruction-free path of entry for endoscopic instruments, and to evacuate surgical smoke.

It is indicated for use in abdominal, thoracic, and pediatric ( $\geq 20$ kg) procedures where insufflation is desired to facilitate the use of various thoracoscopic and laparoscopic instruments by filling the abdominal or thoracic cavity with gas to distend it, by creating and maintaining a gas sealed obstruction-free instrument path and by evacuating surgical smoke. This instrument can also be used to insufflate the rectum and colon to facilitate endoscopic observation, diagnosis, and treatment. The trocar of the AirSeal® iFS System is indicated for use with or without visualization.

### **F. Technological Characteristics**

The AirSeal iFS System is similar to the predicate devices in design, intended use, and indications. Like the predicates, the AirSeal iFS System is a software-driven device intended for insufflation of a surgical cavity. Dedicated modes allow for AirSeal functionality in general and pediatric populations where the patient is  $\geq 20$ kg. The system provides audible and visual indicators to communicate system status, safety controls such as venting, occlusion or overpressure conditions, gas supply, and potential fluid ingress. Dedicated tubesets are designed to allow the system to monitor and maintain the pressure of the surgical cavity based on user settings. The subject and predicate AirSeal Systems utilize dedicated access ports for AirSeal functionality.

### **G. Performance Testing**

Benchtop testing demonstrates the ConMed AirSeal iFS System is substantially equivalent to the PneumoSure and predicate AirSeal iFS System regarding intended use, materials, technology, and performance. Comparison testing included the following utilizing an abdominal and thoracic pediatric ( $\geq 20$ kg) test model:

Performance	Measurement	Comparison
Set pressure	Obtain pressure readings using an insufflation gas flow of 2LPM and 5LPM at set pressure points from 5 – 12mmHg.	Average pressure deviation from set pressure
Initial insufflation	Obtain pressure readings at an insufflation gas flow of 20LPM with set pressure points at 5, 10, and 15mmHg.	Average of maximum pressures and deviation of average maximum pressure from set pressure
Obturator removal	Obtain pressure readings at an insufflation gas flow of 10LPM and a set pressure of 12mmHg after removal of a 5mm and 12mm	Average pressure drop at removal and average pressure overshoot (system compensation)

Performance	Measurement	Comparison
	obturator.	
Instrument insertion	Obtain pressure readings at an insufflation gas flow of 10LPM and a set pressure of 12mmHg after insertion, manipulation, and removal of a test rod representing 5mm and 12mm instruments.	Average pressure drop at removal and average pressure overshoot (system compensation)
Leak compensation	Obtain pressure readings at an insufflation gas flow of 20LPM and set pressures of 5mmHg and 12mmHg with introduced leak rates from 0-10LPM.	Average pressure deviation from set pressure

Design verification testing demonstrates the devices comply with the applicable sections of AAMI/ANSI ES60601-1, and IEC 60601-1-2. Software and system verification test results demonstrate the device meets design specifications, including the following:

- Pressure and flow settings, display, increments
- System response at various insufflation conditions
- GUI settings and responses for various insufflation modes
- System recognition and interaction with accessories

Analyses of these activities conclude the benefits associated with the use of the AirSeal iFS System outweigh the residual risks.

#### **H. Substantial Equivalence**

The differences between the predicate devices and the proposed device do not raise any new risks of safety or efficacy. Supporting information per this premarket submission confirms that the subject AirSeal iFS System is safe and effective for its intended use and is substantially equivalent in design, intended use, principals of operation, and technical characteristics to the Stryker PneumoSure and predicate AirSeal iFS System.