September 20, 2023

CONMED Corporation
Tina Mornak
Manager, Regulatory Affairs
525 French Road
Utica, NY 13502

Re: K230239
Trade/Device Name: AirSeal iFS System
AirSeal dV Solution
Regulation Number: 21 CFR§ 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: II
Product Code: HIF, GCJ
Dated: August 17, 2023
Received: August 17, 2023

Dear Tina Mornak:

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 Roberts -S

Jason R. Roberts, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230239

Device Name
AirSeal iFS System
AirSeal dV Solution

Indications for Use *(Describe)*

AirSeal iFS System

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 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.

AirSeal dV Solution

The AirSeal Robotic Solution (ARS) is intended for use in diagnostic and/or therapeutic endoscopic procedures in conjunction with the ConMed AirSeal iFS and an Intuitive da Vinci Xi or da Vinci X Cannula and Cannula Seal 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 procedures where insufflation is desired to facilitate the use of various laparoscopic and thoracoscopic 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. The obturator of the Cannula Cap is indicated for use with or without visualization.

The ARS System must be used with the Intuitive da Vinci Xi or da Vinci X 8mm Instrument Cannula, an Intuitive Cannula Seal and the AirSeal iFS in AirSeal mode. When used in AirSeal mode, the Cannula Cap and Bifurcated Tube Set are designed to provide CO2 gas delivery with stable pneumoperitoneum and continuous smoke evacuation during robotic assisted laparoscopic and thoracoscopic procedures using the da Vinci Xi or da Vinci X systems. The Bifurcated Filtered Tube Set is used to connect the Cannula Cap and Cannula Seal to the AirSeal iFS.

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

AirSeal iFS System

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

I. SUBMITTER

ConMed Corporation
525 French Road
Utica, NY 13502

Company Contact: Tina Mornak
Manager, Regulatory Affairs
724-518-3191
christinamornak@conmed.com

Date Prepared: September 19, 2023

II. DEVICE NAME

Proprietary Name:	AirSeal iFS System AirSeal dV Solution
AirSeal iFS System Model Numbers:	AS-iFS1, iAS12-100, iAS12-100LPi, iAS12-120, iAS12-120LPi, iAS12-150, iAS12-150LPi, iAS5-100LP, iAS5-120LP, iAS5-75LP, iAS8-100LP, iAS8-120LP, iASB12-100, iASB12-120, iASB5-150, SEM-EVAC, SIM-TUB, ASM-EVAC, ASM-EVAC1
AirSeal dV Solution Model Numbers:	ASM-EVAC1-Bi, iAS8-DV, iAS8-DVL
Common Name:	Insufflator, Laparoscopic; Laparoscope, General & Plastic Surgery
Regulation Name:	Laparoscopic Insufflator
Product Code:	HIF; GCJ
Device Class:	II
Regulation Number:	21 CFR 884.1730; 21 CFR 876.1500

III. PREDICATE/LEGALLY MARKETED DEVICE

Predicate

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)

The predicate device has not been subject to a design-related recall.

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.

The ConMed AirSeal dV Solution (or AirSeal Robotic Solution) consists of the following major components: (1) AirSeal® Cannula Cap with a cannula cap and an obturator (in standard and long lengths), and (2) AirSeal® Bifurcated Filtered Tube Set. The cannula cap, obturator and tube set are sterile, single-use products. The AirSeal dV Solution, in conjunction with Intuitive daVinci Xi\X Cannula and Cannula Seal, is operated in the Airseal Mode with the AirSeal iFS System 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. The ConMed AirSeal dV Solution is a sterile, single use device, primarily composed of polycarbonate, polypropylene, and stainless steel.

IV. INTENDED USE / INDICATIONS FOR USE

AirSeal iFS System

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 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 as sealed obstruction-free instrument path and by evacuating surgical smoke. The 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.

AirSeal dV Solution

The AirSeal Robotic Solution (ARS) is intended for use in diagnostic and/or therapeutic endoscopic procedures in conjunction with the ConMed AirSeal iFS and an Intuitive da Vinci Xi or da Vinci X Cannula and Cannula Seal 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 procedures where insufflation is desired to facilitate the use of various laparoscopic and thoracoscopic 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. The obturator of the Cannula Cap is indicated for use with or without visualization.

The ARS System must be used with the Intuitive da Vinci Xi or da Vinci X 8mm Instrument Cannula, an Intuitive Cannula Seal and the AirSeal iFS in AirSeal mode. When used in AirSeal mode, the Cannula Cap and Bifurcated Tube Set are designed to provide CO2 gas delivery with stable pneumoperitoneum and continuous smoke evacuation during robotic assisted laparoscopic and thoracoscopic procedures using the da Vinci Xi or da Vinci X systems. The Bifurcated Filtered Tube Set is used to connect the Cannula Cap and Cannula Seal to the AirSeal iFS.

V. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device & Predicate Device(s):	Subject Device K230239	Predicate Device K063367
Device Name	CONMED AirSeal iFS System	WOM 45L CORE Insufflator Fl 14
Manufacturer	CONMED	WOM (World Of Medicine)
Device Name	AirSeal iFS System	45L CORE Insufflator F1 14
Regulation Number	21 CFR 884.1730 21 CFR 876.1500	21 CFR 884.1730 21 CFR 876.1500
Product Code	HIF GCJ	HIF GCJ
Device Class/Name	Class II/Insufflator	Class II/Insufflator
Fundamental Scientific Technology	Digital insufflation pressure regulation system	Digital Insufflation pressure regulation system
Intended Use	AirSeal® iFS System is intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas, to establish and maintain a path of entry for endoscopic instruments and to evacuate surgical smoke.	The 45L CORE Insufflator Fl 14 (the "Fl 14) is a C02 insufflator intended for use in diagnostic and/or therapeutic endoscopic procedures to distend a cavity by filling it with gas.
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 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	The 45l core insufflator f114 is a co2 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 f114 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

	indicated for use with or without visualization. The AirSeal Robotic Solution (ARS) is intended for use in diagnostic and/or therapeutic endoscopic procedures in conjunction with the ConMed AirSeal iFS and an Intuitive da Vinci Xi or da Vinci X Cannula and Cannula Seal 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 procedures where insufflation is desired to facilitate the use of various laparoscopic and thoracoscopic 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. The obturator of the Cannula Cap is indicated for use with or without visualization. The ARS System must be used with the Intuitive da Vinci Xi or da Vinci X 8mm Instrument Cannula, an Intuitive Cannula Seal and the AirSeal iFS in AirSeal mode. When used in AirSeal mode, the Cannula Cap and Bifurcated Tube Set are designed to provide CO2 gas delivery with stable pneumoperitoneum and continuous smoke evacuation during robotic assisted laparoscopic and thoracoscopic procedures using the da Vinci Xi or da Vinci X systems. The Bifurcated Filtered Tube Set is used to connect the Cannula Cap and Cannula Seal to the AirSeal iFS.	

The AirSeal iFS System and AirSeal dV Solution are the same as the predicate in intended use of distending a cavity with gas, creating a path for endoscopic equipment, and evacuating surgical

smoke and the expanded pediatric indication is the same as the PneumoSure predicate (inclusive of pediatric population <20kg). Any differences in technological characteristics were evaluated via performance testing, described below.

VI. PERFORMANCE DATA

Benchtop testing was completed to support substantial equivalence to the predicate as it relates to safety and effectiveness. The following tests were conducted to support substantial equivalence for the expanded indication:

- Packaging testing ISO 11607-1
- Software verification and validation IEC 62304
- Electrical safety IEC 60601-1
- Electromagnetic compatibility IEC 60601-1-2 (EMC and Immunity)
- Set pressure
- Initial insufflation
- Obturator removal and Instrument insertion
- Leak compensation

VII. CONCLUSION

The subject AirSeal iFS System and AirSeal dV Solution are substantially equivalent in design, materials, indications for use, principles of operation and technological characteristics to the predicate PneumoSure. Based upon the findings of non-clinical testing, the differences present no issues of safety and efficacy and the subject AirSeal iFS System and AirSeal dV Solution are substantially equivalent to the predicate PneumoSure (K063367).