August 19, 2021

ConMed Corporation
Ally Xu
Lead Specialist, Regulatory Affairs
525 French Road
Utica, NY 13502

Re: K211104
Trade/Device Name: AirSeal dV Solution - AirSeal Cannula Cap and AirSeal Bifurcated Filtered Tube Set
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: Class II
Product Code: HIF, GCJ
Dated: April 12, 2021
Received: April 13, 2021

Dear Ally Xu:

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.
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)*
K211104

Device Name
AirSeal® dV Solution- AirSeal® Cannula Cap and AirSeal® Bifurcated Filtered Tube Set

Indications for Use *(Describe)*
The AirSeal® dV Solution, AirSeal Cannula Cap and AirSeal Bifurcated Filtered Tube Set, is intended for use in diagnostic and/or therapeutic endoscopic procedures in conjunction with the ConMed AirSeal iFS and an Intuitive da Vinci Xi and da Vinci X Cannula 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 (≥ 20kg) 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 AirSeal Cannula Cap and Bifurcated Filtered Tube Set must be used with the Intuitive da Vinci Xi and da Vinci X 8 mm 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.**

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

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# 510(k) Summary

CONMED AirSeal dV Solution

Date Prepared: August 17, 2021

## A. Submitter

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

## B. Company Contact

Ally Xu
Lead Regulatory Affairs
T: (720) 546-8941

## C. Device Name

| | |
|---|---|
| Proprietary Name: | AirSeal dV Solution- AirSeal® Cannula Cap and AirSeal® Bifurcated Filtered Tube Set |
| Common Name: | Disposable Endoscopic Trocar and Cannula<br>Carbon Dioxide Insufflation Tubes for Laparoscopy<br>Endoscopic Insufflator |
| Regulation Name: | Laparoscopic Insufflator |
| Regulation Number: | 21 CFR 884.1730 |
| Product Code: | HIF, GCJ |
| Device Classification: | II |
| Panel: | Obstetrics and Gynecology |

## D. Predicate Device

| | |
|---|---|
| Primary Device Name: | AirSeal iFS System |
| Company Name: | CONMED Corporation |
| 510(k): | K190303 |

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

## E. Device Description

The ConMed AirSeal dV Solution consists of the following major components: (1) AirSeal® Cannula Cap with a cannula cap and an obturator, 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.

### Intended Use / Indications for Use

The AirSeal dV Solution®, AirSeal Cannula Cap and AirSeal Bifurcated Filtered Tube Set, 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 (≥ 20kg) 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 AirSeal Cannula Cap and Bifurcated Filtered Tube Set must be used with the Intuitive da Vinci Xi or da Vinci X 8 mm 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 AirSeal Cannula Cap and Intuitive Cannula Seal to the AirSeal iFS.

## F. Comparison to Predicate Device

The predicate device has the following 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 (≥ 20kg) 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.”

| **Feature** | **AirSeal dV Solution** | **AirSeal iFS System (K190303)** |
|---|---|---|
| Product Code | HIF, GCJ | HIF, GCJ |
| System Components | Cannula Cap/Obturator, Filtered Tube set | Insufflator, Cannula/Obturator, Tube set |
| Gas Flow (LPM) | Adult Range: 1-40 | Adult Range: 1-40 |

| | | |
|---|---|---|
| | Pediatric Range: 0.1-20 | Pediatric Range: 0.1-20 |
| Cannula Cap Inner Diameter | 8 mm | 5, 8, 12 mm |
| Pressure | 5-20 mmHg | 5-20 mmHg |
| Smoke Evacuation Levels | Adult: Low - 3LPM<br>High - 8 LPM<br>Pediatric: Low - 2 LPM<br>High - 5 LPM | Adult: Low - 3LPM<br>High - 8 LPM<br>Pediatric: Low - 2 LPM<br>High - 5 LPM |
| Use Environment | Healthcare Facility | Healthcare Facility |

The indications for use of the subject device are foundationally based on the indications for use of the predicate device. The subject and predicate device have the same intended use of distending a cavity with gas, creating a path for endoscopic equipment, and evacuating surgical smoke. The difference in indications for use does not constitute a new intended use, and the technological characteristics do not raise different questions of safety or effectiveness as compared to the predicate device. Technological differences were evaluated through performance testing, described below.

## G. Summary of Non-Clinical Performance Data

**Biocompatibility**
AirSeal dV Solution has undergone biocompatibility testing in accordance with the 2020 FDA guidance document "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process." Testing included:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)
- Acute Systemic Toxicity (ISO 10993- 11:2017)
- Pyrogenicity (ISO 10993- 11:2017)

Due to identical materials and manufacturing processes, some testing was leveraged from the predicate device. Results of the testing determined that the subject device is non-cytotoxic, non-sensitizing, non-irritating, not systemically toxic and non-pyrogenetic.

**Shelf Life**

The AirSeal dV Solution has a three-year shelf-life based on results of an accelerated aging study. The shelf-life study evaluated the device specifications and package integrity/sterile barrier. The device met all acceptance criteria to support a shelf-life of three years.

**Performance**

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

- Penetration Force

- Flow Rate
- Pressure/Leak Testing

All results demonstrated acceptable performance.

## H. Conclusion

The results of performance testing described above demonstrate that the AirSeal dV Solution is as safe and effective as the predicate device and supports a determination of substantial equivalence.