March 16, 2018

ConMed Corporation
% Michael Daniel
President
Daniel & Daniel Consulting, LLC
340 Jones Lane
Gardnerville, Nevada 89460

Re: K172516
Trade/Device Name: SurgiQuest AirSeal iFS System
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic Insufflator
Regulatory Class: Class II
Product Code: HIF, GCJ
Dated: February 13, 2018
Received: February 14, 2018

Dear Michael Daniel:

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.

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.

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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

6. Indications for Use Statement

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)

K172516

Device Name

SurgiQuest AirSeal iFS System

◦ Indications for Use *(Describe)*

The SurgiQuest 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.

It is indicated 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Premarket Notification 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: K172516

Applicant Information:

Date Prepared:	August 18, 2017
Date Modified:	March 15, 2018
Name:	ConMed Corporation Address: 488 Wheelers Farms Road Milford, CT 06461
Contact Person:	Michael A Daniel, Consultant madaniel@clinregconsult.com
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Office Number:	(775) 392-2970
Facsimile Number:	(610) 545-0799
Alternate Contact:	Lisa B. Anderson, Manager, Regulatory Affairs ConMed Corporation lisaanderson@conmed.com
Mobile Number:	(941) 713-2035

Device Information:

Trade Name:	SurgiQuest AirSeal iFS System
Common Names:	Disposable Endoscopic Trocar and Cannula; Carbon Dioxide Insufflator for Laparoscopy Endoscopic Insufflator
Classification Name(s):	Laparoscopic Insufflator
Product Code/ Regulation:	HIF 21 CFR 884.1730 GCJ
Classification:	Class II

Predicate Device:

- SurgiQuest AirSeal iFS System - K143404

Device Description:

The SurgiQuest AirSeal® iFS System (*cleared as AirSeal® Optical Trocar & Cannula System with integrated Insufflator DPIS 2000*) consists of the following major components: (1) a trocar, (2) a cannula, (3) tube sets, and (4) a micro-processor-controlled insufflation, recirculation and filtration unit (the "AirSeal® iFS"). 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; or (c) Smoke Evacuation Mode. The device contains software. The device is designed for use in Medical Centers, hospitals and medical clinics.

Intended Use

The SurgiQuest 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.

Indications for Use:

It is indicated 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.

Comparison to Predicate Device

The tables on the following pages provide a summary of substantial equivalence between the subject device and the cited predicate. The subject device has the same intended use and identical technological characteristics with no new questions of safety or effectiveness raised. Clinical data are being provided to support safety and effectiveness for thoracic use. The questions remain the same, e.g.,

1) Can the insufflation pressures be adequately controlled and adjusted?
2) Are the blood/tissue contacting materials biocompatible and sterile?
3) Are there any other risks to internal organs or tissues?

Summary Comparison to Predicate:

	Subject Device	**Predicate Device**	**Comparison to predicate and reference devices**
Device Name	SurgiQuest AirSeal iFS System	SurgiQuest AirSeal iFS System	
Manufacturer	SurgiQuest	SurgiQuest	Same
510(k) #	K172516	K143404	N/A
Regulation Number	21 CFR 884.1730	21 CFR 884.1730	Same
Class	Class II	Class II	Same
Classification Advisory Committee	General & Plastic Surgery	General & Plastic Surgery	Same
Device Class/Name	Insufflator	Insufflator	Same
Product Code	HIF, GCJ	HIF, GCJ	Same

	Subject Device	Predicate Device	Comparison to predicate and reference devices
Fundamental scientific technology	Digital insufflation pressure regulation system.	Digital insufflation pressure regulation system	Same
Intended Use	The SurgiQuest 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 SurgiQuest 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.	Same
Indication for Use	It is indicated 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.	It is indicated to facilitate the use of various thoracoscopic and laparoscopic instruments by filling the abdominal 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.	Substantially equivalent based upon clinical evidence provided.

List of Standards Used:

Verification and validation testing was completed in compliance with the following standards:

- AAMI ANSI ES60601-1:2005(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010(R)2012 (Consolidated Text) Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD). FDA recognition number: 19-4
- IEC 60601-1-2:2007/AC:2010, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3). FDA recognition number: 19-2
- IEC 60601-2-18 Edition 3.0 2009-08, Medical electrical equipment – Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment. FDA recognition number: 9-61
- IEC 62304:2015, Medical device software – Software life cycle processes. FDA recognition number: 13-79
- ISO 10993-1:2009(R) 2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (Biocompatibility). FDA recognition number: 2-156

- ISO 10993-5: 2009/(R) 2014, Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity. (Biocompatibility). FDA recognition number: 2-153
- ISO 10993-7:2008, Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals (Including technical corrigendum 1, 2009). FDA recognition number: 14-408
- ISO 10993-10: 2010, Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization. (Biocompatibility). FDA recognition number: 2-173
- ISO 10993-11: 2006/(R)2010, Biological evaluation of medical devices –11: tests for systemic toxicity. (Biocompatibility). FDA recognition number: 2-118
- ISO 11135:2014, Sterilization of heath care products – Ethylene oxide – Requirements for the development, validation, and routine control of a sterilization process for medical devices. FDA recognition number: 14-452
- ISO 11137-1 First edition 2006-04-15, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices (Including: Amendment 1, 2013). FDA recognition number: 14-428
- ISO 11137-2:2013, Sterilization of health care products – Radiation- Part 2: Establishing the sterilization dose. FDA recognition number: 14-409
- ISO 11607-1:2006, Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems. FDA recognition number: 14-454
- ISO 14971:2007, Medical devices – Application of risk management to medical devices. FDA recognition number: 5-40
- AAMI ANSI ST67:2011, Sterilization of health care products – Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled "sterile". FDA recognition number: 14-314

Testing described in this 510(k) consisted of verification of all design input requirements and product specifications. All clinical input requirements were validated.

Summary of Testing Completed:

Bench/*In vitro* Verification Testing:

All system specifications were verified as having been met through extensive bench testing. This testing included confirming all functional and performance attributes of the system met their respective specifications and requirements. This testing included, but was not limited, to confirming compliance with each of the applicable portions of the FDA/industry recognized standards listed in the previous section. This testing included:

Test	Results
Verification AirSeal mode launches automatically after initial insufflation is completed.	Pass
Verification the iFS will maintain the actual pressure within a specified range of the set pressure.	Pass
Verification the AirSeal System venting feature activates appropriately and effectively reduces cavity pressure within the specified time.	Pass
Verification the iFS will maintain an average actual pressure within a specified range of the set pressure when an instrument is inserted into the Access Port and manipulated.	Pass

Clinical/*In vivo* and Simulated Use Testing

All system medical/clinical design input requirements were validated as having been met through extensive performance and simulated use testing. This testing confirmed all functional and performance attributes of the system met their respective design input requirements in compliance with ConMed's design control procedures and systems. This validation testing included but was not limited to real-world clinical evaluation and simulated use testing utilizing bench models of the thoracic cavity simulating pressure and volume conditions.

Article Citations and Summary

Robotically-Assisted Thoracic Surgery / Video Assisted Thoracoscopic Surgery			
Data Source	**Number of Patients**	**Subject Device Used**	**Adverse Events**
Cerfolio *et al.* 2016[1]	8	yes	none
Gonde *et al.* 2017	10	yes	none
Kneuertz *et al.* 2017	20	yes	none
Suda *et al.* 2014	33	yes	none

Summary:

Based upon the Intended Use, Indications for Use, product technical information, performance evaluation, and standards compliance provided in this premarket notification, the SurgiQuest AirSeal iFS Insufflation System, has been shown to be substantially equivalent to the cited predicate.

[1] Confirmed by testimonial letter from the author.