DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 18, 2015

AirSep Corporation
Mr. Ted Vlahopoulos
Regulatory Specialist
260 Creekside Drive
Buffalo, NY 14228

Re: K150930
Trade/Device Name: Deployable Oxygen Generator System - Small (DOGS-S)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: November 12, 2015
Received: November 16, 2015

Dear Mr. Vlahopoulos:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150930

Device Name
Deployable Oxygen Generator System – Small (DOGS-S)

Indications for Use *(Describe)*
The Deployable Oxygen Generator System – Small (DOGS-S) is intended for the administration of supplemental oxygen. This device is not intended for life support nor does it provide any patient monitoring capabilities. The system will be operated by trained personnel.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter:

Airsep Corporation
260 Creekside Drive
Buffalo, NY 14228

Phone: (716) 691-0202

Fax: (716) 691-1255

Registration Number: 1319044

Contact person:

Peter Weisenborn

Quality & Regulatory Manager

Email: peter.weisenborn@chartindustries.com

Preparation Date: 03/31/15

Device Trade Name:

DOGS-S Deployable Oxygen Generation System-Small

Classification Name: Portable Oxygen Generator

Regulation Number: 868.5440

Product Code: CAW

Device Class: Class II

Classification Panel: Anesthesiology and Respiratory Therapy Devices

Predicate Devices:

OMNI 2 (SAROS) from SeQual Technologies / A Chart Industries Company

Product Code: CAW

510(k) number: K083163

Device Description:

The DOGS-S system is a portable battery powered oxygen concentrator that will be operationally used for ground-based medical assemblages, such as the Expeditionary Medical Support (EMEDS), and En-Route Patient Staging System (ERPSS) in deployed scenarios, including wartime operations, deterrence, humanitarian and contingency operations.

Oxygen Concentrator Process

Oxygen concentrators were introduced in the mid-1970s and have become the most convenient, reliable source of supplemental oxygen available today.

The air we breathe contains approximately 21% oxygen, 78% nitrogen, and 1% other gases. In the DOGS-S unit, room air passes through a regenerative adsorbent material called molecular sieve. This material separates the oxygen from the nitrogen and other gases. The result is a constant supply of high concentration supplemental oxygen that is delivered to the patient.

User/Operator Profile:

AirSep's Concentrators are intended to supply supplemental Oxygen to patients suffering from discomfort due to ailments which affect the efficiency of ones lungs to transfer the oxygen in air to their bloodstream. Patients can benefit from supplemental oxygen therapy for respiratory care at home, in the hospital, or at a medical facility. Oxygen Concentrator use requires a physician's prescription, and is not intended for life support use.

DOGS-S was designed for Military Medical Service use in deployed scenarios, including wartime operations, deterrence, humanitarian and contingency operations.

The DOGS-S will be operated by a trained medical technician with respiratory therapy background. In addition to the normal operation of the DOGS-S, the USER/OPERATOR shall have a working knowledge of oxygen concentrators.

Technological Characteristics:

DOGS-S will generate 15 litres per minute (LPM) gaseous supply pressure oxygen with a regulated flow adjustment ranging from 0.5 LPM to 15 LPM (ASTM F1464-93) in 0.5 increments will concentrate oxygen from the atmosphere to a purity of 93% (ASTM F1464-93) United States Pharmacopeia (USP). DOGS-S supplies continuous flow of product through a standard patient distribution port. An operator supplied nasal cannula connects to the distribution port to deliver supplement oxygen to the patient. The device includes a detachable battery and internally contained battery charger. The battery charger is capable of charging the battery while the DOGS-S is off or being used while plugged into AC power source. DOGS-S is a portable unit using handle accessory and/or transit case with handles. DOGS-S will be provided with a non-reusable box for initial shipment and a reusable carrying case.

Below is the comparison table.

Substantial Equivalence Comparison:	**DOGS-S**	**OMNI 2 (SAROS)**
Intended Use:	The Deployable Oxygen Generator System – Small (DOGS-S) is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities. The system will be operated by trained personnel.	The Omni 2 Oxygen System is intended for the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.
Technological Characteristics:		
Major Components:		
Compressor:	• Brushless DC motor • Type – Rotary Swing	• Brushless DC motor • Type - Scroll
PSA Valve type:	• (PSA) Pressure Swing Adsorption • Adsorption - Molecular sieve • 5 Bed design • Type - Rotary	• (PSA) Pressure Swing Adsorption • Adsorption - Molecular sieve • 5 Bed design • Type Rotary
Battery:	• Lithium Ion	• Lithium Ion
Other Characteristics Comparisons:		
Electrical requirements:	• AC 100/240V 50/60Hz • Battery 674 Whr peak	• AC (100VAC, 50/60 Hz) • Power Cartridge (Battery) 88 Whr
Purity:	• 93% +/-3% USP	• 93% +/-3% USP
Flow Rate:	• 0.5 to 15LPM continuous flow • control panel readout	• 1 to 3LPM continuous flow • control panel readout

Filtration:	• Dust Compressed Inlet HEPA	• Dust Compressed Inlet HEPA
Output pressure:	• 10.0 psig nominal	• 5.0 psig nominal
Power consumption:	• 550 Watts @ 15LPM	• 128 Watts @ 3LPM
Weight:	• 37 lbs. w/o battery	• 10 lbs. w/o battery
Diameter:	• 10″	• 4.4″
Height:	• 33″	• 26″
Sound Level:	• <70dBA	• <59dBA
Oxygen Purity Warning:	• <85%	• 70-85%
Oxygen Purity Low:	• <85%	• <70%
Alarm indicators:	• Low Oxygen purity • O2 Flow High or Low • Low power indicator (Battery) • Unit malfunction	• Low Oxygen purity • O2 Flow High or Low • Low power Cartridge (Battery) • Unit malfunction
Enclosure:	• MATERIAL: G/10 F/R FIBERGLASS TUBE. • PC \ ABS	• MATERIAL: G/10 F/R FIBERGLASS TUBE. • PC / ABS

SUMMARY:

This summary demonstrates that the Device has no significant technological differences from the predicate device that would adversely affect product safety and effectiveness, i.e. all technological characteristics are covered.

Accessories:

The following components are part of the DOGS-S submission; a battery pack / lithium ion, power supply, power cord, handle, and manuals. There are no accessories that have received prior FDA 510k clearance.

Intended Use:

The Deployable Oxygen Generator System – Small (DOGS-S) is intended for the administration of supplemental oxygen. This device is not intended for life support nor does it

provide any patient monitoring capabilities. The system will be operated by trained personnel. The differences in language in the intended use for the SAROS and DOGS-S are minor.

Testing:

The **DOGS-S** has been tested and verified in various phases, internal testing, verification and validation as well as external testing and validation. The design was verified throughout the design process. Risk analysis was done, appropriate measures were implemented and their effectiveness verified. External test house was used to confirm compliance to EMC requirements and standards for electrical safety.

The testing confirms the Deployable Oxygen Generator System – Small (DOGS-S) meets the ISO 80601-2-69 standards for Oxygen Concentrator devices. Testing demonstrates that the product is in compliance to: AAMI ES60601-1 3rd Edition Medical electrical equipment—Part:1 General Requirements for Basic Safety and Essential Performance and to IEC 60601-1-2 3rd Edition Medical Electrical Equipment, Part 1: General Requirements for Safety-Collateral Standard: Electrical Compatibility - Requirements and Tests.

Performance Data:

The oxygen flow rate and purity at the operating pressure was tested and verified in the Performance Bench Testing section of this submission, the instruction manual and in accordance with

- ISO 80601-2-69 Medical Electrical Equipment, Part 2-69
- IEC 60601-1 Safety Requirements (Medical Electrical Equipment Part 1: General Requirements)
- IEC 60601-1-2 EMC (Electro Magnetic Compatibility Testing)
- ISO 62304 Medical Device Software-Software Life-Cycle Processes
- ISO 10993-1 Biological Evaluation of Medical Devices
  - Cytotoxicity
  - Sensitization
  - Irritation
- Compliance with USP 93% +/-3%
- Particulate Matter Testing
- Volatile Organic Compound Testing

- Ozone Testing
- MIL-STD-810f
- MIL-STD-810g
- MIL-STD-461e

The test platform ensures compliance to recognized consensus standards and therefore does not raise new questions of safety and effectiveness.

Conclusion:

The **DOGS-S** performance tests demonstrate substantial equivalence to the predicate device. The performance tests results also confirm ability to provide 93% +/- 3% USP oxygen for supplemental oxygen use only.