K101154

MAR 2 8 2011

510(k) Summary

Submitter

Airsep Corporation
401 Creekside Drive
Buffalo, NY 14228
Phone: (716) 691-0202
Fax: (716) 691-4141

Registration Number: 1319044

Contact person

Peter Weisenborn

Email: pweisenborn@airsep.com

Preparation Date

March 25, 2011

Device

Trade Name:

Centrox, Ultrox and Reliant Oxygen Concentrators
Classification Name: Generator, Oxygen.
Regulation Number: 868.5440
Product Code: CAW
Device Class: Class II
Classification Panel: Anesthesiology and Respiratory Therapy Devices

Predicate Devices

NewLife Intensity from AirSep Corporation
Product code: CAW
510(k) number: K960309

Portable Oxygen Generator with Medical Air (POGS 33C) from On Site Gas Systems, Inc.
Product code: CAW
510(k) number: K063454

Device Description

Air contains 21 % oxygen, 78% nitrogen, 0.9% argon, and 0.1% other gases. AirSep PSA Oxygen units separate this small percentage of oxygen from the compressed air through a unique Pressure Swing Adsorption (PSA) process. The compressed air flows through a filter assembly before the air enters the adsorber vessels. A particulate/foam filter removes condensed water, oil, dirt, scale, etc. from the feed air, and then, a separate coalescing filter (if present) removes additional oil and water vapor.

The oxygen generator uses in its adsorber vessels an inert ceramic material called molecular sieve to separate compressed air into oxygen and other gases. The unique properties of molecular sieve allow it to attract, or adsorb, nitrogen physically from air under pressure. This allows oxygen to exit the adsorbers as a product gas.

While one adsorber produces oxygen, the other depressurizes to exhaust the waste gases it adsorbed (collected) during the oxygen production cycle. The entire oxygen generating process is completely regenerative, which makes it both reliable and virtually maintenance-free. The molecular sieve does not normally require replacement.

The medical devices in this submission refer to the following oxygen concentrators manufactured by AirSep Corporation:

Model	Flow (scfh)	Oxygen Delivery Pressure (psig)
Centrox	32	50
Ultrox	17	20
Reliant	17	50

All of these devices are designed to deliver the oxygen with USP 93 % purity. Centrox and Reliant units are also available for cylinder filling option. Ultrox is used only to fill cylinders.

Centrox, Ultrox and Reliant units are comprised of an air compressor that uses ambient air to produce higher pressure feed air.

These models have the same indications for use. Together these products are referred to as Device.

The device is intended to be USP 93% oxygen generator. As such, to assure the purity, an Oxygen Analyzer is integrated in each device and an alarm is activated if the purity is outside of the safe range.

Intended Use

The intended use of the device is to generate and deliver USP 93% oxygen for supplemental oxygen use only or filling cylinders. The device must not be used for or with any life-supporting applications. The device is intended to be used only by trained personnel in hospitals, health care facilities or remote locations where bottled oxygen is not readily available. The instruction manual of the device recommends an alternate source of supplemental oxygen in the event of a power outage, alarm condition, or mechanical failure.

Technological Characteristics

The comparison table is provided as a summary of the technological characteristics relative to the predicate devices. Items like intended use, principle of operation, oxygen purity, inlet pressure and flow rates are compared. All major components used in the system are also compared. The primary difference between the device and the respective predicate devices is in the flow rates which is a result of the size of the units. The performance of the device to produce the desired flowrates at specified purity and delivery pressure has been validated. The summary of the comparison table demonstrates that the device has no significant differences from the predicate devices that would adversely affect product safety and effectiveness.

Testing

The device 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.

Performance Data

The oxygen flow rate and purity at the operating pressure as specified in the instruction manual was tested and verified. The variation of oxygen purity and output pressure with the amount of overdrawing, the variation in parameters due to failure of components, the effect of improper valve cycling on the device parameters were tested and the ability of every device to deliver USP 93% oxygen was verified.

Independent laboratory testing also verified that the oxygen purity was in accordance with USP 93% and that the total Volatile organic compounds (VOC's) and particulates were well below accepted standards.

The results of this testing prove the safety and effectiveness of the device.

Conclusion

The device performance tests demonstrate substantial equivalence to the predicate devices. The performance tests results also confirm ability to provide USP 93% oxygen for supplemental oxygen use only and for filling cylinders safely and effectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Mr. Peter Weisenborn
Vice President-Resources and Regulatory Affairs
Airsep Corporation
401 Creekside Drive
Buffalo, New York 14228-2085

MAR 28 2011

Re: K101154
Trade/Device Name: Centrox, Ultrox and Reliant Oxygen Concentrators ("Device")
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: March 21, 2011
Received: March 24, 2011

Dear Mr. Weisenborn:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Applicant: Airsep Corporation

510(k) Number (if known): K101154

Device Name: Centrox, Ultrox and Reliant Oxygen Concentrators (***"Device"***)

Indications For Use:

The intended use of the Device is to generate and deliver USP 93% oxygen for supplemental oxygen use only or filling cylinders. The device must not be used for or with any life-supporting applications.

The Device is intended to be used only by trained personnel in hospitals, health care facilities or remote locations where bottled oxygen is not readily available.

The instruction manual of the device recommends an alternate source of supplemental oxygen in the event of a power outage, alarm condition, or mechanical failure.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

(Optional Format 3-10-98)

510(k) Number: K10 1154