SEP 27 2005

K051887

SECTION 11: PREMARKET NOTIFICATION [510(K)] SUMMARY

Date: February 21, 2005

Applicant: Carleton Life Support Systems, Inc.
2734 Hickory Grove Road
Davenport, IA 52804

Phone: 563-383-6299
FAX: 563-383-6107

Contact: Gary Byrd, Medical Oxygen Engineering Manager

Trade Name: Patient Ventilation Oxygen Concentrating System, High Flow (PVOCS HF)

Common Name: Oxygen Concentrator

Classification Name: Generator, Oxygen , Portable

Establishment Registration Number: 3002840531

Legally Marketed Device to which Substantial Equivalence is claimed: Patient Ventilation Oxygen Concentrating System (PVOCS) K013223

Description

The PVOCS HF is a dual-mode medical gas system which supplies both oxygen-enriched gas at 93 ± 3% oxygen (hereafter referred to as OXY 93% or USP Oxygen 93%) and medical-grade air (MED AIR). In the High Flow OXY 93% mode, the PVOCS HF can supply up to 30 lpm of oxygen and 30 lpm of medical-grade air, and in the Low Flow OXY 93% mode oxygen mode, up to 20 lpm of oxygen and 75 lpm of medical-grade air. The system requires a separate compressed air supply from which oxygen is concentrated using pressure swing adsorption (PSA) techniques with synthetic zeolite. The oxygen is supplied at two low-pressure (6-psig) ports for patient respiration via nasal cannula and four moderate-pressure (50-psig) ports for patient ventilators. A storage plenum (purge tank) is included in the product line to ensure that short-term, high-demand flows do not cause a drop in oxygen concentration or pressure drops below rated output pressure in the product gas. The medical-grade air is provided to four ports at 50 psig by filtering the compressed air supply and drying it using PSA techniques.

Indications for Use

The PVOCS HF system is intended to provide respiratory gases to include pre and post operative respiratory oxygen, pneumatic drive gas for ventilators and anesthesia machines, and oxygen enrichment for ventilators and anesthesia machines. It may be used

in military field hospitals and other applications where oxygen stored in high pressure cylinders or liquid oxygen is not available, practical or safe to use. It is appropriate for use by military personnel only.

Technological Summary

The PVOCS HF uses the same technology, the pressure swing adsorption process, as the predicate device to produce USP 93% oxygen and medical grade air.

Performance

Non-clinical bench testing by Carleton Life Support Systems, Inc. verified that the system is capable of producing up to 30 lpm of of USP 93% oxygen and 30 lpm of medical grade air in the High Flow mode and 20 lpm of USP93% oxygen and 75 lpm of medical grade air in the Low Flow mode.

Conclusions

Based upon the nonclinical bench testing and analysis provided, the PVOCS HF is substantially equivalent to the predicate device PVOCS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2005

Mr. Gary Byrd
Carleton Life Support Systems Inc.
2734 Hickory Grove Road
Davenport, Iowa 52804-1203

Re: K051887
Trade/Device Name: Patient Ventilation Oxygen Concentrating System, High Flow
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: July 7, 2005
Received: July 12, 2005

Dear Mr. Byrd:

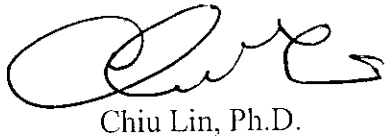
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051887

Device Name: Patient Ventilation Oxygen Concentrating System, Hi Flow (PVOCS HF)

Indications For Use: The PVOCS HF system is intended to provide respiratory gases to include pre and post operation respiratory oxygen, pneumatic drive gas for ventilators, and anesthesia machines, and oxygen enrichment for ventilators and anesthesia machines. It may be used in military field hospitals and other applications when oxygen stored in high pressure cylinders or liquid oxygen is not available, practical, or safe to use. It is appropriate for use by military personnel only.

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

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