K082829
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SECTION 12: PREMARKET NOTIFICATION [510(K)] SUMMARY

Date: December 19, 2008

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

DEC 22 2008

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

Contact: Gary Byrd, Mechanical Engineering Manager

Trade Name: Aircraft Medical Oxygen Generation System (AMOGS)

Common Name: Oxygen Concentrator

Classification Name: MEDEVAC Use Oxygen Generator

Product Code: OLF

Regulation Number: 8685440

Establishment Registration Number: 3002840531

Legally Marketed Devices to which Substantial Equivalence is claimed:
Deployable Oxygen Generation System – Medium (DOGS-M) developed by Carleton Life Support Systems, cleared under submittal K020330 and Total O2 manufactured by Chad Therapeutics, cleared under submittal K971889.

Description

The AMOGS system is designed to provide supplemental oxygen meeting USP93% requirements using the Pressure Swing Adsorption (PSA) process on the HH-60M MEVAC helicopter. It is comprised of an oxygen concentrator, monitor panel, backup oxygen cylinder and heat exchanger and filter assembly. The AMOGS utilizes engine bleed air and electrical power from the aircraft resources to provide oxygen-enriched breathing gas for medical evacuation applications. The bleed air is conditioned by the heat exchanger and filter assembly and then routed to the concentrator which produces oxygen-enriched breathing gas. The backup oxygen cylinder provides oxygen-enriched breathing gas during periods in which the concentrator is not operating or the peak demand exceeds the concentrator rated capacity. The monitor panel provides operational status of the concentrator and back up cylinder.

Indications for Use

The AMOGS system is intended to provide oxygen enriched gas generated by the pressure swing adsorption process to patients who may have difficulty extracting oxygen from air that they breathe while on board the HH-60M MEDEVAC helicopter. The system may be used to provide medical support to the full spectrum of deployed scenarios including wartime operations, deterrence and contingency operations, peacetime engagement, crisis response and humanitarian relief operations by trained personnel.

The oxygen supplied by the AMOGS is supplemental and is not considered to be life supporting or life sustaining.

This device is not intended to be used in the presence of flammable anesthetics nor is it intended to be sterilized.

There are no contraindications.

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Technological Summary

The primary function of the AMOGS is to provide supplemental oxygen for military medical evacuation applications. The AMOGS uses the same technology, the pressure swing adsorption process, as the predicate devices to produce USP 93% oxygen. Both the Total O2 and the AMOGS use pneumatic pressure intensifiers to compress the gas while the DOGS-M uses an electrically driven compressor to provide the same function. The technological characteristics of the AMOGS and its intended use to supply supplemental oxygen, are basically the same as the predicate devices and raises no new questions of safety or effectiveness.

The primary difference between the AMOGS and the predicate devices are the output capacity and pressure.

Performance

Non-clinical bench and flight testing by Carleton Life Support Systems, Inc. and the US Army verified that the system is capable of producing USP 93% oxygen and delivering it to downstream medical devices at pressures of 55 psig. Independent laboratory testing also verified that oxygen purity was in accordance with USP 93% and that total gaseous hydrocarbons and halogenated hydrocarbons and particulates were below accepted standards.

Conclusions

Based upon the testing and analysis provided, the AMOGS is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 2008

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

Re: K082829
Trade/Device Name: Aircraft Medical Oxygen Generation System (AMOGS)
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: OLF
Dated: September 11, 2008
Received: September 25, 2008

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, Ph. D
Division 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: TBD

Device Name: Aircraft Medical Oxygen Generation System (AMOGS)

Indications For Use:

The AMOGS system is intended to provide oxygen enriched gas generated by the pressure swing adsorption process to patients who may have difficulty extracting oxygen from air that they breathe while on board the HH-60M MEDEVAC helicopter. The system may be used to provide medical support to the full spectrum of deployed scenarios including wartime operations, deterrence and contingency operations, peacetime engagement, crisis response and humanitarian relief operations by trained personnel.

The oxygen supplied by the AMOGS is supplemental and is not considered to be life supporting or life sustaining.

This device is not intended to be used in the presence of flammable anesthetics nor is it intended to be sterilized.

There are no contraindications.

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

510(k) Number: K082829