K071581

Summary for Backpack Medical Oxygen System (BMOS)

Company/Owner Name:	**Essex Cryogenics of MO., Inc.**
Company Address:	8007 Chivvis Drive, 63123 St., Louis, MO.
Fax:	314-832-8208
Phone:	314-832-8077 (306)
Registration Number:	1937980
Point of Contact:	Elizabeth Hunnicutt, Quality Engineer / Regulatory Affairs
Date of Summary:	June 1, 2007
Trade Name:	Backpack Medical Oxygen System (BMOS)
Common Name:	portable oxygen device

JUL 11 2007

Device Classification Regulation Number and Regulatory Status:
Anesthesiology - Therapeutic Devices
Portable Liquid Oxygen Unit
CFR 21 § 868.5655
Class II

Legally Marketed Device which Substantial Equivalence is claimed:
Next Generation Portable Therapeutic Liquid Oxygen Converter (NPTLOX)
2004 – **510(k) K033000**

Description: The BMOS is a portable thermally insulated container that provides, when filled with liquid oxygen (LOX), an uninterrupted supply of supplemental oxygen gas to be inhaled by the patient. BMOS is operated by trained emergency response personnel to administer patients with variable amounts of gaseous oxygen in doses measured in liters per minute (LPM).

Indications for use: The BMOS is intended to be used by emergency response personnel in military and commercial fields to provide an emergency source of supplemental oxygen for one patient while being transported from a crisis situation to a health care facility. The BMOS is not intended to be a life sustaining or a life-supporting device.

Substantial Equivalence Comparison with the NPTLOX: Both devices include a vacuum insulated cryogenic container designed to store liquid oxygen. Both deliver gaseous oxygen at a nominal 50-psi pressure near ambient temperature. Neither design operates on any software, or external power. Neither design emits ionizing, non-ionizing, sonic, or light radiation. Neither unit requires sterilization.
The major modifications are a decrease in liquid oxygen capacity, a lowered flow (LPM) capability and a reduced capability to support multiple patients, which resulted in a decreased overall size and weight.

Testing: Extensive capability, performance, and environmental testing have been accomplished on the BMOS with no issues arising regarding its safety and efficacy. The combined testing and analysis of results provides assurance that the device meets its specifications and is safe and effective for its intended use.

Upon completion of Qualification testing, we have determined that the BMOS meets the FDA criteria for substantial equivalence to the predicate device.

Elizabeth Hunnicutt

Elizabeth Hunnicutt, Quality Engineer/Regulatory Affairs

JUNE 01, 2007

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 11 2007

Essex Cryogenics of Missouri, Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

Re: K071581
Trade/Device Name: Backpack Medical Oxygen System
Regulation Number: 21 CFR 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: June 26, 2007
Received: June 27, 2007

Dear Mr. Job

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 (240) 276-3150 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): _____

Device Name: Backpack Medical Oxygen System

Indications for Use: The BMOS is intended to be used by emergency response personnel in military and commercial fields to provide an emergency source of supplemental oxygen for patient/s while being transported from a crisis situation to a health care facility. The BMOS is not intended to be a life sustaining or a life-supporting device.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K071581