Essex Cryogenics of Missouri, Inc.
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tel: 314.832.8077 • fax: 314.832.8208
www.essexind.com • www.medlox.com K101272

AUG 2 0 2010

510(k) Summary

1. Owner Information

Owner's Name:	Essex Cryogenics of Missouri, Inc.
Address:	8007 Chivvis Drive
	St. Louis, Missouri 63123-2395
Phone Number:	314-832-8077
Fax Number:	314-832-8208
Contact Person:	Kenneth L. Seise
Date:	April 30, 2010

2. Medical Device Information

Trade Name:	Mass Oxygen Distribution System (MODS)
Common Name:	Portable Liquid Oxygen System
Classification Name:	Portable Liquid-Oxygen Unit

3. Substantial Equivalence to Predicate Medical Device

The MODS is substantially equivalent to the Next Generation Portable Therapeutic Liquid Oxygen System (NPTLOX) (K033000).

4. Medical Device Description

The MODS has a portable, thermally insulated container of liquid oxygen (LOX) that is intended to supplement gases to be inhaled by a patient, and is accompanied by tubing intended for connection to an oxygen mask.

The MODS is portable. The MODS houses the thermally insulated stainless steel container, which stores liquid oxygen, and is set on casters while the accompanying unit, the patient distribution kit, is encased with a handle. The MODS converts liquid oxygen (99.9% pure) from the insulated container through a heat exchanger into gaseous oxygen and finally the gaseous oxygen is distributed through the tubing in the accompanying interconnect hose or hose reel assembly and ultimately through the tubing in the accompanying patient distribution kit. After connecting the tube end to an oxygen mask, cannula, simulator ventilator, or other similar medical device (none of these devices is included in the MODS) the patient can inhale the gaseous oxygen.

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The accompanying patient distribution kit has ten outlet ports that are capable of delivering oxygen to a maximum of ten patients. Multiple patient distribution kits can be used to deliver oxygen to more than patients.

The MODS has the capacity to store seventy-five (75) liters of LOX and convert it to a gaseous state. It can be filled using a fill harness and current commercially available LOX storage/filling systems such as a variable gas/liquid (VGL) cylinder. When using the MODS with external LOX cylinders, the system will run indefinitely under normal operating conditions (indoors at room temperature) as long as the LOX cylinders are rotated between each of two MODS external hookup ports. When filled with LOX, the MODS provides an uninterrupted supply of oxygen for delivery to patients at a maximum system flow rate of four hundred fifty (450) liters per minute (LPM) and, when connected to a patient distribution kit, at an individual patient flow rate of one-half (0.5) to fifteen (15) LPM. The nominal operating system pressure of the MODS is two hundred (200) psig and, when connected to a patient distribution kit, the individual hose pressure is fifty (50) psig.

5. Intended Use of Medical Device

The MODS is intended to convert liquid oxygen to gaseous oxygen (99.9% based on medical grade liquid oxygen) for delivery to a patient at one-half (0.5) to fifteen (15) LPM and fifty (50) psig.

6. Comparison to Predicate Medical Device

The NPTLOX is the predicate medical device to which MODS is compared. Both are portable. Personnel can move an NPTLOX device by picking up the unit by its handles and walking with it while personnel can move a MODS device by pushing it on its casters. Both the NPTLOX and MODS devices are similar in that they include a thermally insulated container. Both containers are designed built, and tested per CFR 49 CFR 178.57 and are housed in aluminum sheet metal enclosures that contain heat exchangers that convert the liquid oxygen to gaseous oxygen. Both devices have ports that can be connected to tubing intended for connection to an oxygen mask or other similar medical device to ultimately supplement gases to be inhaled by a patient.

Both devices can be monitored for pressure and liquid oxygen quantity.

The main differences in the NPTLOX and MODS are in the container size and LOX capacity. The NPTLOX container is a sphere that is approximately thirteen and one-half (13.5) inches in diameter with a LOX capacity of 20 liters while the MODS container is a sphere that has a diameter of approximately twenty one (21) inches and a LOX capacity of seventy five (75) liters.

Thus both the NPTLOX and MODS are portable liquid-oxygen units that function the same but are different sizes.

7. Medical Device Tests

Essex Cryogenics of Missouri, Inc. engineering personnel completed extensive MODS capability, performance, and environmental testing with no issues arising regarding its safety and efficiency. The combined testing and analysis of results provides assurance that the device meets it specifications and is safe and effective for its intended use.

8. Conclusions

Based on review of the design and test results, Essex Cryogenics of Missouri, Inc. believes that no significant differences exist between this medical device, MODS, and the predicate medical device, NPTLOX, and therefore the MODS is as safe, as effective, and performs as well as, or better than, the NPTLOX.

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. Ken Seise
Essex Industries, Incorporated
8007 Chivvis Drive
St. Louis, Missouri 63123

AUG 2 0 2010

Re: K101272
Trade/Device Name: Mass Oxygen Distribution System
Regulation Number: 21 CFR 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: June 15, 2010
Received: June 16, 2010

Dear Mr. Seise:

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

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Indications for Use Statement

510(k) Number (if known):

Device Name: Mass Oxygen Distribution System

Indications for Use: The MODS is intended to convert liquid oxygen to gaseous oxygen (99.9% based on medical grade liquid oxygen) for delivery to a patient at one-half (0.5) to fifteen (15) LPM and fifty (50) psig.

Prescription Use X AND/OR Over-The-Counter Use_____
(CFR Title 21, Part 801, Subpart D) (CFR Title 21, Part 801, Subpart C)

(PLEASE DON 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: K101272