ESSEX™
INDUSTRIES

K130068

JUL 19 2013

510(k) Summary

1. Owner Information

Owner's Name:	Essex Industries, Inc. d/b/a Essex Cryogenics of Missouri
Address:	8007 Chivvis Drive
	St. Louis, Missouri 63123-2395
Phone Number:	314-338-8533
Fax Number:	314-832-8208
Contact Person:	Kenneth L. Seise
Date:	January 5, 2013 (Revised July 19, 2013)

2. Medical Device Information

Trade Name: Dismounted Medical & Supplemental Oxygen System (DMOS)
Common Name: Portable Liquid Oxygen System
Classification Name: Portable Liquid-Oxygen Unit
Classification Code: II
Product Code: BYJ
CFR Section: 21CFR 868.5655

510(k): K130068

3. Substantial Equivalence to Predicate Medical Device

The DMOS is substantially equivalent to the Backpack Medical Oxygen System (BMOS) (K071581).

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4. Medical Device Description

Physical and performance characteristics

The DMOS, when filled with liquid oxygen, will be used to provide medical oxygen treatment to injured personnel or provide supplemental oxygen to operator during dismounted operations above 10,000 feet MSL. The following general requirements apply.

a) The DMOS shall supply 93% oxygen concentration when filled from Oxygen Generator System (OGS).

b) The DMOS shall be capable of delivering gaseous oxygen to one patient at a maximum flow rate of 15 ambient Liters Per Minute (LPM).

c) The DMOS shall be capable of connecting to medical mask or cannula to supply oxygen during operations above 10,000 feet MSL.

d) The DMOS shall be capable of delivering oxygen to one patient at a flow rate of 5 LPM for a minimum duration of 4 hours.

e) The DMOS operating pressure shall be 50 ± 5 pounds per square inch gauge (psig).

f) The liquid oxygen (LOX) capacity shall be 1.4 liters.

g) The DMOS shall operate up to 35,000 feet MSL.

h) The overall weight of the DMOS, including LOX, shall be less than 16 lbs.

i) The oxygen delivery pressure shall be monitored and displayed.

j) The liquid oxygen quantity shall be monitored and displayed.

k) Any power required by the DMOS shall be self-contained.

l) The DMOS shall have the capability to be filled with LOX by standard Department of Defense (DoD) and North Atlantic Treaty Organization (NATO) servicing connectors.

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m) The DMOS shall be refilled in 10 minutes or less from the Oxygen Generator System (OGS).

How the device functions

The DMOS provides for storing of 1.4 liters of liquid oxygen and converting this liquid into its gaseous state. The gaseous oxygen is capable of being delivered in controlled amounts to provide medical treatment to injured patients and uncontrolled amounts to drive respiratory medical devices or supplemental oxygen in high altitude. The DMOS is capable of being filled with liquid oxygen from the Oxygen Generator System (OGS) and with current liquid oxygen storage/ filling stations.

DMOS contains liquid oxygen (LOX). The DMOS contains a thermally insulated container of liquid oxygen (LOX) that is intended to supplement gases to be inhaled by a patient. The DMOS supports medical devices provided by the user including masks, cannulas, and Bag Valve Mask (BVM) being attached to the flow control patient outlets. An empty portable liquid oxygen unit is a device, while the oxygen contained therein is a drug.

The DMOS is portable. The handle on the front control make the DMOS portable. The DMOS can be carried onboard, tied down, transported and operationally perform on various aircraft and ground vehicles.

The DMOS converts liquid oxygen from its insulated container through its heat exchanger into gaseous oxygen and finally the gaseous oxygen is available for distribution from an outlet port on the user interface. After connecting a tube assembly connector of a mask, cannula, and Bag Valve Mask (BVM) to an outlet port, masks, cannulas, and BVMs or other similar medical device (none of these devices is included in the DMOS) the patient can inhale the gaseous oxygen.

5. Indications for Use of Medical Device

The DMOS is intended to convert liquid oxygen to gaseous oxygen for delivery to a patient and/or for delivery to rescue personnel to supplement environmental oxygen at high altitudes while being carried by a rescue personnel at one-half (0.5) to fifteen (15) liters per minute (LPM) and fifty (50) pounds per square inch gauge (psig).

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6. Comparison to Predicate Medical Device

The BMOS (K071581) is the predicate medical device to which DMOS (K130068) is compared. Indications for Use for BMOS is that 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 a patient while being transported from a crisis situation to a health care facility. The BMOS is not intended to be a life sustaining or life-supporting device.

- Both the submission device and predicate device convert liquid oxygen to gaseous oxygen
- Both devices can be used in military and commercial applications
- Both devices supply supplemental oxygen to a patient
- Both flow at one-half (0.5) to fifteen (15) liters per minute (LPM) and fifty (50) pounds per square inch gauge (psig)
- The only difference between the two devices is that DMOS is capable of supplying oxygen to rescue personnel in situations where they themselves need additional oxygen when they are in high altitude, mountainous region

BMOS & DMOS are both portable. Personnel can move a BMOS device by picking up the unit by the handle on the front face and walking with it while personnel can move a DMOS device by in the same manner. Both the BMOS and DMOS devices are similar in that they include a thermally insulated container. Both containers are designed built, and tested per 49 CFR §178.57, Specification 4L welded insulated cylinders, 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 differences in the BMOS and DMOS are in the container size and LOX capacity. The BMOS container is a cylinder that is approximately 13.1 inches long and 5.0 inches in diameter with a LOX capacity of 2 liters while the DMOS container is a cylinder that is approximately 12.3 inches long and 4.4 inches in diameter with a LOX capacity of 1.4 liters.

The DMOS has an additional parachute port, which the BMOS does not have, that allows the military rescue personnel to plug in his/her parachutist mask for additional oxygen when they are in high altitude, mountainous region.

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DMOS is a slightly smaller version of the BMOS, where both systems function exactly the same, with the exception that DMOS has the capability to provide oxygen at high altitude for rescue personnel.

Performance/ Characteristics	DMOS (K130068)	BMOS (K071581) (PREDICATE DEVICE)
Indications for Use	The DMOS is intended to convert liquid oxygen to gaseous oxygen for delivery to a patient and/or for delivery to rescue personnel to supplement environmental oxygen at high altitudes while being carried by a rescue personnel at one-half (0.5) to fifteen (15) liters per minute (LPM) and fifty (50) pounds per square inch gauge (psig).	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 a patient while being transported from a crisis situation to a health care facility. The BMOS is intended to be a life sustaining or life-supporting device.
Target Population	Adult	Adult
Where Used	Military & commercial emergency response /rescue	Military & commercial emergency response /rescue
Dimensional Envelope	Height = 5.5" Width = 7.25" Depth = 17.0"	Height = 6.5" Width = 7.5" Depth = 17.5"
System Weight	15.3 lbs when filled with LOX	18.5 lbs max when filled with LOX
Delivery Rate (outlet flow)	15 LPM @ 50 PSIG	15 LPM @ 50 PSIG
Delivery Temperature	Within +10/-20 °F of low ambient (-40 °F) and within +10/-65 °F of high ambient (130 °F) at the outlet ports.	Within +10/-20 °F of ambient at outlet ports.
Delivery Temperature Alarm	No alarm	No alarm
# Person Carry	1-Person—unit has one handle.	1-Person—unit has one handle.
Energy Used	Battery operated	Battery operated
LOX Quantity Indicator	Battery powered indicator (One 9V)	Battery powered indicator (Six AA)
Low Quantity Alarm	No alarm	No alarm
Outlet Pressure	50 PSIG outlet pressure	50 PSIG outlet pressure
Outlet Pressure Alarm	No alarm	No alarm
Outlet Ports	2 Outlet Ports (DISS 1240 & Female Dixon Quick-Disconnect)	1 Outlet Port (DISS 1240)
Flow Control Outlet Ports	1 Flow Control Valve (0.5-15 LPM, with 12 settings)	1 Flow Control Valve (0.5-15 LPM, with 12 settings)
Human Factors	Single-person carry	Single-person carry
Standards Met	DOT-4L (Production Units)	DOT-4L
Sterility / Shelf Life	N/A	N/A
Electrical Safety	Tested IAW MIL-STD-810G	Tested IAW MIL-STD-810F

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Performance/ Characteristics	DMOS (K130068)	BMOS (K071581) (PREDICATE DEVICE)
Medical Devices Compatibility	Commercial Mask Commercial Cannula Flow Control Valve (0.5-15 LPM, with 12 settings)	Commercial Mask Commercial Cannula Flow Control Valve (0.5-15 LPM, with 12 settings)
Fill Connection	Standard Military CRU-50/A connection which connects with the military standard CRU-59/E connector on all the LOX filling equipment	Standard Military CRU-50/A connection which connects with the military standard CRU-59/E connector on all the LOX filling equipment
Storage Capacity	1.4 Liters of LOX	2 Liters of LOX
Operating Temperature	-40°F to 130°F	32°F to 120°F
Storage Temperature	-40°F to 130°F	-40°F to 160°F

7. Medical Device Tests

Essex Industries, Inc. Engineering personnel completed extensive DMOS capability, performance, and environmental testing with similar acceptable results as that of BMOS and so have determined that DMOS is substantially equivalent to BMOS. The combined testing and analysis of results provides assurance that the device meets it specifications and meets its intended use. See the following table for bench tests and standards.

Bench Test	Test or Analysis	Test Standard
Insulation Resistance	Test	
Visual & Dimensional Examination	Test	
Leakage	Test	
Quantity Indicator Performance	Test	
Weight & Capacity	Test	
Fill Time	Test	
Buildup Time	Test	
Parachutist Mask Delivery Rate	Test	
Patient Delivery Rate	Test	
Patient Delivery Temperature	Test	
Delivery Duration	Test	
Normal Evaporative Rate	Test	
High Temperature Operation	Test	MIL STD 810 Rev. G
Low Temperature Operation	Test	MIL STD 810 Rev. G
Altitude	Test	MIL STD 810 Rev. G

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Bench Test	Test or Analysis	Test Standard
Helicopter Vibration	Test	MIL STD 810 Rev. G
Aircraft Vibration	Test	MIL STD 810 Rev. G
Ground Vehicle Vibration	Test	MIL STD 810 Rev. G
Functional Shock	Test	MIL STD 810 Rev. G
Crash Hazard Shock	Test	MIL STD 810 Rev. G
Safety Drop	Test	MIL STD 810 Rev. G
Ballistic Test	Analysis	
Salt Fog	Analysis	
Humidity	Analysis	
Rain	Analysis	
Freezing Rain	Analysis	
Blowing Snow	Analysis	

8. Conclusions

Based on review of the design and test results, Essex Industries, Inc. believes that no significant differences exist between this medical device, DMOS, and the predicate medical device, BMOS, and therefore DMOS is substantially equivalent to BMOS.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 19, 2013

Essex Industries, Inc. d/b/a Essex Cryogenics of Missouri
C/O Mr. Kenneth Seise
Quality Assurance/Regulatory Compliance Manager
8007 Chivvis Drive
St. Louis, MO 63123-2395

Re: K130068
Trade/Device Name: Dismounted Medical & Supplemental Oxygen System
Regulation Number: 21 CFR 868.5655
Regulation Name: Portable Liquid-Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: June 17, 2013
Received: June 19, 2013

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.

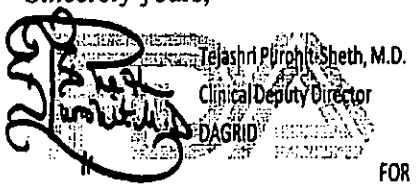
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 contact 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. 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

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, 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: Dismounted Medical & Supplemental Oxygen System

Indications for Use: The DMOS is intended to convert liquid oxygen to gaseous oxygen for delivery to a patient and/or for delivery to rescue personnel to supplement environmental oxygen at high altitudes while being carried by a rescue personnel at one-half (0.5) to fifteen (15) liters per minute (LPM) and fifty (50) pounds per square inch gauge (psig).

Anya C. Harry

Digitally signed by Anya C. Harry
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.07.19 13:26:23 -04'00'

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

510(k) Number: K130068

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)

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