K131990

510(k) Summary
Page 1 of 7
6/27/2013

Essex Industries, Inc. d/b/a
Essex Cryogenics of MO
8007 Chivvis Drive
St. Louis, Missouri 63123

Tel: (314) 338-8533
Fax: (314)832-8208

Official Contact:	Kenneth L. Seise – Quality Assurance/Regulatory Compliance Manager
Proprietary or Trade Name:	OGL
Common/Usual Name:	Portable Oxygen Generator
Classification Name/Code:	CAW- Portable Oxygen Generator 21CFR 868.5440 Class II
Device:	Oxygen Generator Liquefier- (OGL)
Predicate Device:	Portable Therapeutic Oxygen Concentrator System (PTOCS) - K022684

Device Description:
The OGL is a device that generates 93% USP oxygen gaseous, liquefy it into LOX and store up to 40 liters of LOX. It OGL is a single module that weighs approximately 730 LBS empty or 830 full of LOX. The system is 52" long, 33" wide and 48" tall (55" tall if the wheels are deployed). The system has to forklift pockets to allow the system to be moved by a forklift. The system also has retractable wheels that allows for one or two persons to easily move the device on a flat smooth surface.

The OGL requires only 200-240 VAC, 50/60 Hz 30 amp single phase power supply for operation. The system is very simple to operate. The control panel has a mode switch that allows the user to make liquid oxygen (LOX), generate gaseous oxygen for the oxygen gas port or transfer the liquid oxygen to a separate device. The control panel also has fault indicators if there is a problem with the system, emergency stop button, hour meter, Dewar pressure gauge and LOX quantity gauge.

Intended User
Healthcare providers

510(k) Summary
Page 2 of 7
6/27/2013

Patient Population
This device generates liquid oxygen to be transferred into portable LOX systems, so a patient population is not indicated.

Indications for Use:
The OGL is intended to be used by emergency response personnel in military and commercial applications to produce emergency source of 93% USP liquid oxygen (LOX) which will be transferred into portable LOX systems. The portable LOX systems are used as an emergency source of supplemental oxygen for patient(s) while being transported for a crisis situation to a health care facility. This medical device is for supplemental oxygen and is not intended to sustain or support life.

Environment of Use:
Environments of Use: Locations where LOX oxygen generation is desired, e.g. military, hospital.

Contraindications:
There are no known contraindications.

Predicate Device Comparison:
The OGLwas compared to the predicate PTOCS (K022684) in the device comparison table below.

Device Comparison

Table 5.1

Performance/ Characteristics	OGL	PTOCS K022684 (PREDICATE DEVICE)
Indications for Use	The OGL is intended to be used by emergency response personnel in military and commercial applications to produce emergency source of 93% USP liquid oxygen (LOX) which will be transferred into portable LOX systems. The portable LOX systems are used as an emergency source of supplemental oxygen for patient(s) while being transported for a crisis situation to a health care facility. This medical device is for supplemental oxygen and is not intended to sustain or support life.	Provides supplemental therapeutic oxygen to a patient in a military field hospital setting.
Environment of use	Used by emergency response personnel in military and commercial applications and by military medical personnel.	Used by emergency response personnel in military and commercial applications and by military medical personnel.
Energy Used	200-240, 50/60 Hz	110, 60 Hz & 208-220, 60 Hz
Technology	Oxygen is concentrated by the use of molecular sieve beds / Pressure Swing Adsorption (PSA)	Oxygen is concentrated by the use of molecular sieve beds and Pressure Swing Adsorption (PSA)
Portability/Human Factors	Forklift portable or can be move by one person with the wheels deployed on a level surface.	Compressor Module "A" 4 man portable Compressor Module "B" 4 man portable Oxygen Concentrator Module 4 man portable High Pressure Fill Module 4 man portable
Standards Met	IEC 60601-1, IEC 60601-1-2	IEC60601-1
Sterility / Shelf Life	N/A	N/A
Electrical Safety	Tested IAW MIL-STD-810, & IEC60601-1	Tested IAW MIL-STD-810, & IEC60601-1
Operating Temperature	0°F to 120°F	32°F to 90°F
Storage Temperature	0°F to 130°F	-40°F to 158°F
Humidity	Up to 95%	Up to 95%
Storage Humidity	Up to 100%	Up to 100%

510(k) Summary
Page 4 of 7
6/27/2013

Performance/ Characteristics	OGL	PTOCS K022684 (PREDICATE DEVICE)
Dimensional Envelope	OGL Height (Wheels Retracted) = 48.0" Height (Wheels Deployed) = 54.5" Width = 33.0" Depth = 52.0" See Figure 12-7	Compressor Module "A" Height = 28" Width = 27" Depth = 44" See Figure 12-8 Compressor Module "B" Height = 27" Width = 24" Depth = 44" See Figure 12-8 Oxygen Concentrator Module Height = 42" Width = 22" Depth = 31" See Figure 12-8 High Pressure Fill Module Height = 27.5" Width = 23.5" Depth = 34.5" See Figure 12-8
System Weight	OGL Empty = 730 LBS Full (with LOX) = 830 LBS	Compressor Module "A" = 298.8 LBS Compressor Module "B" = 149.6 LBS Oxygen Concentrator Module = 283.3 LBS High Pressure Fill Module = 153.0 LBS
Power Requirements	OGL Power = 200-240 VAC Supply Frequency = 50/60 Hz Phase = Single Phase Watts = 6.3 kW MAX	Compressor Module "A" & "B" Power = 208-220 VAC Supply Frequency = 60 Hz Phase = Three Phase Watts = 6.93 kW MAX Oxygen Concentrator Module Power = 110 VAC Supply Frequency = 50/60 Hz Watts = 100 W High Pressure Fill Module Power = 110 VAC Supply Frequency = 60 Hz Watts = 600 W
Oxygen Purity	93% USP	93% USP

510(k) Summary
Page 5 of 7
6/27/2013

Performance/ Characteristics	OGL	PTOCS K022684 (PREDICATE DEVICE)
Oxygen Gas Outlet	# of Ports = 1 Port Type = Male DISS 1240 Flow Rate = 11 LPM Pressure = 7 PSI	# of Ports = 3 Port Type = Female Schrader Quick Disconnect Flow Rate = 45 LPM Pressure = 50 PSIG
Medical Devices Compatibility	High Pressure Cylinder Fill	Commercial Mask Commercial Cannula Flow Control Valve (0.5-15 LPM, with 12 settings)
LOX Quantity Indicator	Mechanical Gauge	None
Fill Connection	Standard Military CRU-59/E connection which connects with the military standard CRU-50/A connector on all the portable LOX storage systems	None
LOX Storage Capacity	40 Liters of LOX	None
Alarms/Indicators	Three Fault Indicators. (If any problem occurs with system, the system will shut down and it will light the appropriate fault indicators.)	Compressor Module "A" & "B" Low Pressure Indicator Power Out of Phase Indicator Oxygen Concentrator Module Low Pressure Indicator High Pressure Indicator Low Oxygen Purity Indicator Oxygen Sensor Fault Indicator High Pressure Fill Module Low Pressure Indicator Back up Activated Indicator
Software	Has software with a microprocessor that controls the entire system.	

Differences Between Other Legally Marketed Predicate Devices:
The OGL is viewed as substantially equivalent to the predicate device because: The OGL uses the exact same technology and has similar indications for use. The differences that exist between the devices are insignificant in the terms of safety or effectiveness.

Indications –
The OGL is intended to be used by emergency response personnel in military and commercial applications to produce emergency source of 93% USP liquid oxygen (LOX) which will be transferred into portable LOX systems. The portable LOX systems are used as an emergency source of supplemental oxygen for patient(s) while being

transported for a crisis situation to a health care facility. This medical device is for supplemental oxygen and is not intended to sustain or support life.

Discussion – These indications are similar to the predicate PTOCS (K022684).

Prescriptive – The OGL and predicate are both prescriptive.

Design and Technology – The OGL has equivalent design and features as the predicate and has the identical technology to the predicate.

Performance and Specifications – The OGL has equivalent specifications of performance as the predicate.

Compliance with standards – The OGL and predicate device declare compliance with IEC 60601-1 and IEC 60601-1-2.

Materials –
The air contacting materials have been cleared in prior 510(k)s as described in **Section 15**

Patient Population –
Neither the OGL or predicate have a define patient population.

Non-Clinical Testing Summary:

We have performed bench tests and found that the OGL met all requirements specifications and standards requirements and was found to be equivalent in comparison to the predicate.

Testing is documented in the Qualification Test Report (QTR-50C-0103-5,-7) in **Section 18** - Performance Bench Testing.

Functional testing, e.g. pressure, delivery rate, normal evaporation rate and environmental testing, e.g. vibration testing, of the OGL was acceptable and proves that the device functions as intended and functions safely. Functional testing, e.g. display readout accuracy and fault indicator testing, and environmental testing, e.g. high and low temperature operation and storage testing, was acceptable and proves that the device functions as intended and functions safely. Testing includes:

- Visual Examination
- Oxygen Purity
- Liquefaction Rate and Capacity

- Liquid Transfer
- Dimensional Examination
- Weight
- Power
- Normal Evaporative Rate (NER)
- Component Bonding
- High Temperature Operation
- Low Temperature Operation
- High Temperature Storage
- Humidity
- Rain
- Salt Fog
- Shipping Vibration
- ISO 8359:1996 Oxygen concentrators for medical use - Safety requirements

Clinical Testing Summary:
No clinical testing

Substantial Equivalence Conclusion
Essex maintains that the OGL is substantially equivalent to the predicate PTOCS (K022684) in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards

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

February 21, 2014

Essex Industries, Incorporated
Mr. Paul Dryden
Regulatory Consultant
8007 Chivvis Drive
St. Louis, MO 63123

Re: K131990
Trade/Device Name: Oxygen generator Liquefier (OGL)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: February 18, 2014
Received: February 19, 2014

Dear Mr. Dryden:

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

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

As required, we have prepared the Indications for Use statement on a separate page.

Indications for Use Statement

510(k) Number: K131990 (To be assigned)

Device Name: **Essex Industries Oxygen Generator/Liquefier (OGL)**

Indications for Use:

Device Name: Oxygen Generator/Liquefier

The OGL is intended to be used by emergency response personnel in military and commercial applications to produce emergency source of 93% USP liquid oxygen (LOX) which will be transferred into portable LOX systems. The portable LOX systems are used as an emergency source of supplemental oxygen for patient(s) while being transported for a crisis situation to a health care facility. This medical device is for supplemental oxygen and is not intended to sustain or support life.

Environments of Use: Locations where LOX oxygen generation is desired, e.g. military, hospital.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K131990

FDA

Anya C. Harry -S
2014.02.21 14:27:30
-05'00'