K022689

SEP 11 2002

Essex Cryogenics of Missouri, Inc.
A SUBSIDIARY OF ESSEX INDUSTRIES, INC.
8007 CHIVVIS DRIVE • ST. LOUIS, MO 63123-2395
(314) 832-8077 • FAX (314) 832-8208
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510(k) Summary for PTOCS

July 29, 2002

Applicant: **Essex Cryogenics of MO., Inc.**
8007 Chivvis Drive,
Saint Louis, MO 63123
Fax: 314-832-8208
Phone: 314-832-8077 (306)
Contact: Elizabeth Hunnicutt, Quality Engineer / Regulatory Affairs
314-832-8077 ext. 306
email: ehunnicutt@essexind.com

Trade Name: Portable Therapeutic Oxygen Concentration System (PTOCS)
Common Name: Oxygen Concentrator
Establishment Registration Number:
1937980
Manufactured at: Same as Applicant
Classification Name: Oxygen Concentrator
Product code CAW, CFR 21 § 868.5440
Class II
Reason for 510(k): Initial Release of PTOCS

Legally Marketed Device, which Substantial Equivalence is claimed:
Patient Ventilation Oxygen Concentrating System K013223
Invacare 6 Oxygen Concentrator K904087

Description: The Portable Therapeutic Oxygen Concentration System (PTOCS) has been designed to accommodate Military Personnel with a source of supplemental oxygen in a setting where liquid oxygen may be unavailable. Aeromedical Evacuation and ground based medical missions require medical support systems capable of providing therapeutic oxygen. The gaseous oxygen generator will also be required to provide oxygen at the prescribed flow rates and pressures required to operate the oxygen driven equipment included in the AFMS deployable medical assemblages. Requirements are based on the deployable oxygen system, operational requirements document that has been issued by the United States Air Force.

This system is based on the Pressure Swing Adsorption principle and uses a molecular sieve to separate gases from the filtered ambient air. The oxygen is stored and delivered to the patient(s) through one of three ports (1/2 to 15 lpm settings) with a maximum litre per minute flow of 45 total at 50 psig. The oxygen concentration purity level is at 93% minimum, with an oxygen purity level average of 95%. Included with the generator is a secured accessory kit consisting of 20 feet of medical grade oxygen hose and flow regulators for each outlet.

Indications For Use: Provides supplemental therapeutic oxygen to a patient in a military field hospital setting.

Conclusion: Non-clinical bench testing conducted by Essex Cryogenics of MO., Inc, as provided is conclusive in establishing substantial equivalence of the PTOCS to the predicate devices on which SE is claimed.

Prepared and Submitted by:

Elizabeth Hunnicutt Quality Engineer/Regulatory Affairs July 29, 2002
Date

By signing my name, I certify that I am the responsible party for submitting regulatory information to the FDA on behalf of Essex Cryogenics. Requests for additional information should be made to me at my above noted email or phone numbers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 2002

Ms. Elizabeth Hunnicutt
Quality Engineer / Regulatory Affairs
Essex Cryogenics of MO., Incorporated
8007 Chivvis Drive
Saint Louis, Missouri 63123

Re: K022684
Portable Therapeutic Oxygen Concentration System (PTOCS)
Regulation Number: 868.5440
Regulation Name: Generator, Oxygen, Portable
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: July 29, 2002
Received: August 12, 2002

Dear Ms. Hunnicutt:

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. In addition, if you wish to change or expand your current indications for use to include non-military environments, you will need to submit a new 510(k) premarket notification, and receive FDA clearance prior to marketing the device.

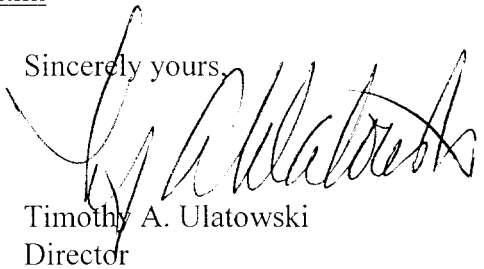
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022684

Device Name:
Portable Therapeutic Oxygen Concentration System

Indications For Use:
Provides supplemental therapeutic oxygen to a patient in a military field hospital setting.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)** OR **Over-the-Counter Use** ___ **(Optional Format 1-2-96)**

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

510(k) Number: K022684