AIR LIQUIDE

APR 1 0 2006

510 (k) Summary
EZ-OX Plus Portable Oxygen System
510(k) Number: K053117

Submitted in accordance with the requirements of SMDA 1990 and 21 CFR807.92

1. **APPLICANT'S/SUBMITTER'S INFORMATION**

Air Liquide America LP
2700 Post Oak Blvd. Suite 1800
Houston, Texas 77056

Direct Phone:	800-624-8000
Internet:	www.us.airliquide.com
Establishment Registration No:	Pending
Contact:	Angie Beyer, Compliance Specialist
Contact's Phone:	713-624-8268
Contact's Fax:	713-624-8580

2. **DATE**

February 7, 2006

3. **DEVICE INFORMATION**

Trade/Proprietary Name:	EZ-OX Plus
Common Name:	Portable Oxygen Delivery System
Device Name:	Cylinder, Compressed Gas, and Integrated Valve-Regulator
Classification Panel:	Cardiovascular and Respiratory Devices
Classification Number:	unclassified
Product Nomenclature:	Cylinder, Compressed Gas, and Integrated Valve-Regulator
Product Code(s):	ECX

4. **DEVICE CLASSIFICATION**

Empty Compressed gas cylinders and compressed gas cylinder with valve assemblies are unclassified devices, and reviewed by the Anesthesiology and Respiratory Devices Branch, Division of Anesthesiology, General Hospital, Infection Control, and Dental Devices.

Gas Cylinder pressure regulators and gas pressure gauges are Class 1 devices and exempted from pre-market notification.

5. **PREDICATE DEVICE(s)**
   - 510(k) No: K033897: MEDICYL-E-Lite Portable Medical Oxygen System (Linde)

6. **DEVICE DESCRIPTION**

The EZ-OX Portable Oxygen System is a solution for supplying Oxygen USP using a device comprised of an integrated valve-regulator, flow meter and medical E-Oxygen aluminum cylinder with handle and shroud all integrated into a single unit. Key specifications include hose barb connection, protective shroud , carrying handle, easy to read content gauge, indexed flow meter, integrated valve-regulator and usage chart label with safety instructions. This design allows medical personnel the ability to provide patient care and treatment sooner without delays caused by the need to mount a conventional regulator.

7. **INDICATIONS FOR USE**

The EZ-OX Plus is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults. When administered by properly trained personnel for oxygen deficiency and resuscitation, the EZ-OX Plus is for emergency use only. For all other medical applications, the device is Rx only.

8. **DEVICE FUNCTION**

Compressed gas cylinder with an adjustable valve to control the flow of Oxygen to the patient.

9. **TECHNOLOGICAL CHARACTORISTICS**

A summary comparison of technological characteristics, including design and materials is provided in the table below:

Parameter	EZ-OX Plus	MEDICYL-E-Lite
Valve/Regulator		
Low Flow Settings	Yes (≥ .5L)	Yes
Flow Between Settings	No	No
Cylinder on/off	No	Yes
Filling Port	Active	Active
Contents Gauge	Active	Non-active
Filters	4	3
Pressure Design	3000 psi (max)	4350 psi
Excess Flow Device	Yes	Yes
Single stage piston style	Yes	Yes
Guard		
Hand Grip	1 grip	2 grip
Access Ports	Yes	Yes
Flow selector/ hose barb/ gauge aligned	Yes	Yes
Color	Green	Green

Parameter	EZ-OX Plus	MEDICYL-E-Lite
Height (guard and integrated valve-regulator)	7"	6.75"
Cylinder		
Cylinder Sizes	D, E	D, E
Weight (E) (product)	950 gr	900gr
Materials/construction	Aluminum	Aluminum

The manufacturer believes that the technological characteristics of the EZ-OX Plus portable oxygen system is substantially similar to those of the predicated device.

10. **PERFORMANCE DATA**

The aluminum cylinders conform to the requirements of 49 CFR 178.46, Specification seamless aluminum cylinders.

11. **SAFETY TESTING**

The ASTM G 175 evaluates the regulator's sensitivity to ignition by subjecting the regulator to **two basic tests.**

One test requires subjecting the regulator to pressure shock tests according to ISO 10524. The integrated valve-regulator was tested for resistance to ignition in accordance to European Standard EN-738-3. Testing for resistance to ignition by EN-738-3 is equivalent to the ignition test in ISO 10524. The test requires subjecting the regulator to maximum temperature and to pressure shocks, up to maximum pressure, to demonstrate no ignition or damage to internal parts or areas within the regulator. As required by the standard, these pressure shock tests are conducted in various configurations of the regulator valve and shut-off valve.

The second test evaluates the regulator's behavior when subjected to a positive ignition source to simulate ignition by particle impact. The integrated valve-regulator has been tested for ignition in accordance to EN-738-3, equivalent to ISO 10524. These recognized standards do not require ASTM G 175 test using a positive ignition source to simulate ignition by particle impact. However, the regulator is designed to decrease the risk of ignition by particle impact by incorporating a 60 micron filter at the filling connection, a 60 micron filter at the valve-regulator inlet, and a 20 micron filter in the seat of the regulator.

12. **STATEMENT OF SUBSTANTIAL EQUIVALENCE**

Based upon the safety and performance testing and compliance with voluntary standards, the manufacturer believes that the EZ-OX Plus portable oxygen delivery system is substantially equivalent to the predicate device, and does not raise any new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 10 2006

Ms. Angie Beyer
Air Liquide Healthcare America
2700 Post Oak Boulevard, Suite 1800
Houston, Texas 77056

Re: K053117
Trade/Device Name: EZ-OX Plus Portable Oxygen Delivery System
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: None
Product Code: ECX
Dated: February 9, 2006
Received: March 3, 2006

Dear Ms. Beyer:

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 (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.

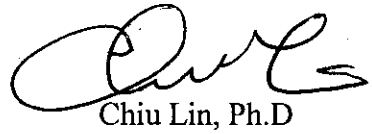
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 continue 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 Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): K053117

Device Name: EZ-OX Plus Portable Oxygen Delivery System

Indications For Use:

The EZ-OX Plus is an integrated portable oxygen delivery system intended to provide supplemental oxygen to adults; a pressure regulator, flow meter and medical E-Oxygen cylinder with handle and shroud all integrated into a single, lightweight unit. Key specifications include hose barb connection, protective cap, carrying handle, easy to read content gauge, indexed flow meter, integrated regulator and usage chart label with safety instructions. Medical personnel can concentrate on providing patient care and treatment sooner without delays caused by the need to mount a regulator. With no assembly needed and the easy-to-use design, it is easy to operate.

For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx only. Compressed gas cylinders in service or in storage shall be stabilized or otherwise secured to prevent falling and rolling.

Prescription Use ____X___ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

K053117