U.S. Department
of Transportation

Pipeline and Hazardous Materials
Safety Administration

DEC 10 2008

1200 New Jersey Ave., SE
Washington, DC 20590

Mr. Stuart H. Bassine
President and Senior Technical Engineer
OxLife LLC
141 Twin Springs Rd.
Hendersonville, NC 28792

Ref. No. 08-0237

Dear Mr. Bassine:

This is in response to your September 25, 2008 letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a device your company calls the Oxlife Independence Oxygen Concentrator.

You state in your letter, supporting documentation, and a subsequent conversation with a member of my staff that the device is a portable oxygen concentrator intended to supply concentrated oxygen for adult patients requiring supplemental oxygen. This device consists of a lightweight, portable oxygen concentrator with an integrated oxygen delivery valve for continuous flow or pulse delivery. The process by which oxygen is provided is called molecular sieve absorption technology. The maximum pressure of the oxygen exerted within the device is less than 17 psia during normal operation at a range from -10° C to 131° C. The device can be powered by multiple power sources, including AC, DC or rechargeable battery power. The battery pack consists of 7 cells with 1.14 grams of lithium content each, or a total of 7.98 total equivalent lithium content, and no other hazardous materials. The lithium polymer rechargeable battery pack has been tested pursuant to the United Nations Manual of Tests and Criteria and is packaged in a manner to prevent short circuits when offered for transport or carried onboard passenger aircraft. You ask whether this device is regulated as a hazardous material under the HMR.

Based on the information provided, the Oxlife Independence Oxygen Concentrator is not currently subject to the HMR because it meets the following criteria:

1. The pressure of the oxygen in the device does not exceed 40.6 psia at 20 °C;

2. The lithium polymer battery used to operate the device meets the requirements of the HMR;

3. The portable oxygen concentrator contains no other materials subject to the HMR; and

4. The battery pack is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (for example, by the effective insulation of exposed terminals).

It should also be noted that Federal Aviation Administration (FAA) approval is required before these electronic devices are used by passengers on board aircraft. For further assistance, you may contact Mr. Dave Catey, Aviation Safety Inspector for the FAA Air Carrier Operations Branch (AFS-220) by phone at (202)-267-3732 or email at david.catey@faa.gov.

I hope this satisfies your inquiry. If we can be of further assistance, please contact us.

Sincerely,

Susan Gorsky
Acting Chief, Standards Development
Office of Hazardous Materials Standards

OxLife LLC.

"We put the O2 in GO2"

Foster
§173.115
§173.185
Battery
08-0237

September 25, 2008

Mr. Edward T. Mazzullo
Director, Office of Hazardous Materials Standard
U.S. DOT/PHMSA (PHH-10)
1200 New Jersey Avenue, SE East Building, 2nd Floor
Washington, DC 20590

We would like to request a formal letter of interpretation that our portable oxygen concentrator model Independence manufactured by OxLife LLC is exempt as hazardous material according to the rules of 49 CFR part 100-180

The device is a portable oxygen concentrator that is intended to supply concentrated oxygen for adult patients requiring supplemental oxygen.

This product (KXIN001) has FDA clearance on 4/16/2008 and is manufactured in accordance with FDA Quality System regulations and Quality Management Systems in accordance with ISO 13485:2003 and MDD93/42 Annex II.

The product contains less than 8 grams of lithium (small battery) and maximum internal pressure is less than 17 psi and contains no other material subject to the HMR. Attached is the device description, technical information, and description of battery specifications to help guide you on understanding the operation of the device.

I look forward to answering your questions and I can be reached at:

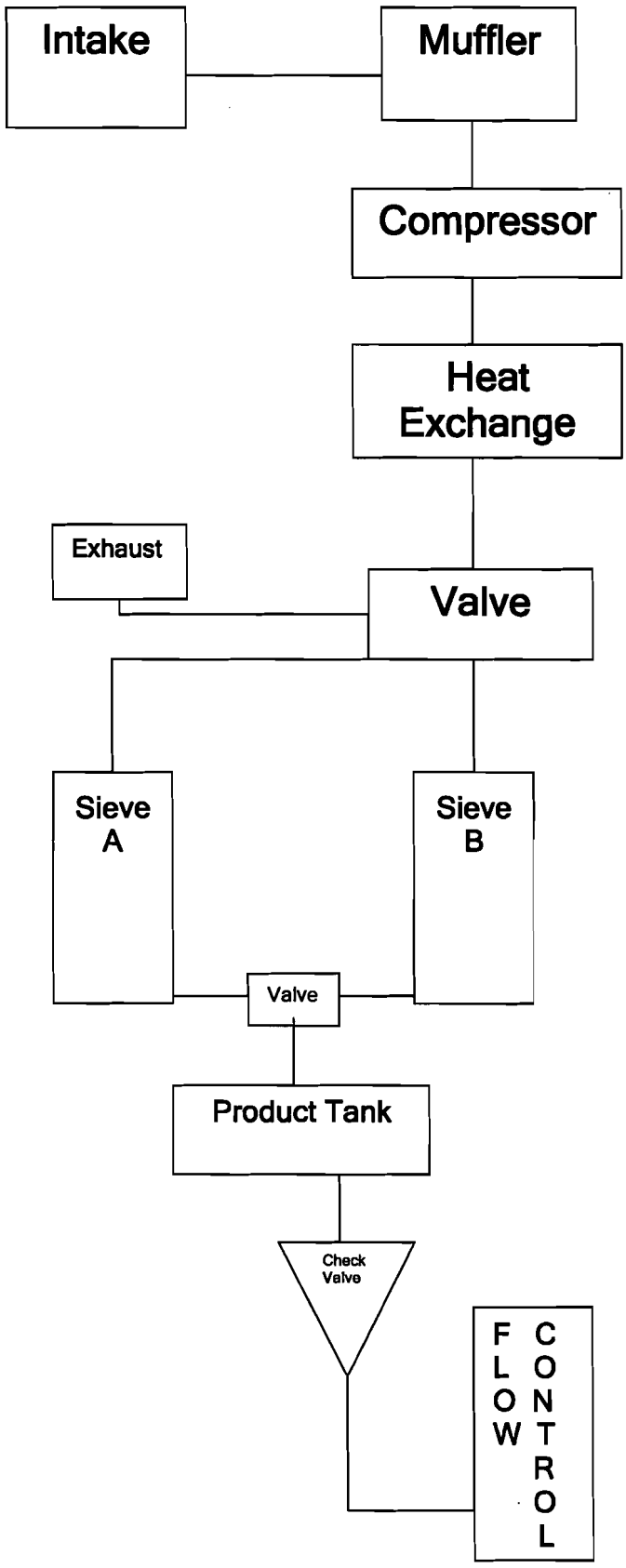
OxLife LLC
141 Twin Springs Rd
Hendersonville NC 28792
Attention: Stuart Bassine - Sr. Technical Engineer
Margaret Poteat - Regulatory Affairs
(828) 684-7353
oxlife@bellsouth.net

Sincerely,

Stuart H Bassine
President and Sr. Technical Engineer
Attachments: A-General Operations (1 Page)
B-FDA 510k (7 Pages),
C-Battery Manufacture (3 Pages)

Attachment A

GENERAL OPERATIONS



Attachment B
FDA 510K Clearance Letter

6 Pages Attached PDF

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Margaret K. Poteat
General Manager/ Management Representative
OxLife LLC
141 Twin Springs Road
Hendersonville, North Carolina 28792

APR 16 2008

Re: K080082
Trade/Device Name: Oxlife Independence Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: June 21, 2007
Received: January 17, 2008

Dear Ms. Poteat:

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.

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.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

10.0 510(k) Summary

K080082

10.1	Submitters Name:	OxLife LLC
10.2	Submitters Address:	141 Twin Springs Rd Hendersonville NC 28792
10.3	Submitters Phone & Fax:	828-684-7353 ph. 828-684-8990 fx.
10.4	Contact Person:	Margaret K. Poteat General Manager/Management Representative
10.5	Date Summary Prepared:	January 7, 2008
10.6	Trade/Proprietary Name:	OxLife Independence™ Oxygen Concentrators
10.7	Common/Usual Name:	Oxygen Concentrator
10.8	Classification Name:	Portable Oxygen Concentrator

10.9 Comparison to Currently Marketed Devices:

The OxLife Independence Oxygen Concentrator is substantially equivalent to the SeQual Eclipse Model 1000 K013931

10.10 Device Description:

The Oxlife Independence Oxygen Concentrator is used on a prescriptive basis by patients requiring supplemental oxygen. Patients may include but are not restricted to those with chronic obstructive pulmonary disease (COPD). The device is not intended to be life sustaining or to be life supporting. It is used with a nasal cannula to channel oxygen from the device to the patient. The concentrator and the nasal cannula are non-sterile.

The Oxlife Independence Oxygen Concentrator provides approximately 90% oxygen to the patient on continuous to 3 and on a conserver flow basis at an "equivalent" rate of 1.0 liters per minute to 6.0 liters to minute.

The Oxlife Independence Oxygen Concentrator is capable of continuous use in a home, institution, vehicles and various mobile environments.

Power options include 110-220 VAC, 12-14 VDC or rechargeable batteries.

The Oxlife Independence Oxygen Concentrator uses molecular sieve adsorption technology. Ambient air is drawn thru particle filters by a compressor and forced thru molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed and nitrogen is desorbed from molecular sieve, allowing it to adsorb again during next

cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, a valve, and timers are used to make the system function.

Oxygen is delivered to the patient on a continuous flow basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. Oxlife Independence Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, thru a final filter, into the connected nasal cannula and onto the patient.

The design of the Oxlife Independence Oxygen Concentrator has focused on maximizing efficiencies and miniaturizing components to enable continuous duty use and to provide minimal weight and battery operation for mobile use.

The basic technology of the Oxlife Independence Oxygen Concentrator is equivalent to other approved oxygen concentrators. The principles of operation are equivalent to the predicate device noted in the submission.

10.11 Indications for Use:

Indications For Use: The OxLife Oxygen Concentrators are indicated for the administration for supplemental oxygen.

10.12 Technological Characteristics:

The Oxlife Independence Oxygen Concentrator utilizes well established technologies. Molecular sieve/pressure swing adsorption technology has been used for many years to produce oxygen. Demand flow delivery systems have been in use on portable oxygen sources for many years. The capability of AC,DC or rechargeable battery power has also been in use.

Technologies utilized by the Oxlife Independence Oxygen Concentrator brings forth no new questions of safety and effectiveness. These technologies are also currently being used in the identified predicate device.

Bench top performance testing has demonstrated that the Oxlife Independence Oxygen Concentrator is equivalent to the SeQual Eclipse Model 1000 K013931

10.13 Performance Data:

The results of the oxygen concentration testing confirm that the oxygen output of the modified devices meets specifications and is substantially equivalent to the predicate device. Also, the inverter provides adequate power to run the devices from a 12 Volt DC power source.

10.14 Conclusion:

Based on the design, performance specifications and testing and intended use, the Oxlife Independence Oxygen Concentrator are substantially equivalent to the currently marketed devices.

Attachment 2
8.0 Statement of Indications for Use

Indications for Use

510 (k) Number: K080082

Device Name: Oxlife Independence Oxygen Concentrator

Indications For Use: The OxLife Oxygen Concentrators are indicated for the administration for supplemental oxygen.

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

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

510(k) Number: K080082

ATTACHMENT C
LETTERS FROM BATTERY MANUFACTURE

2 Pages Attached PDF

HERS Precise Products Inc.

Address: No.10, Alley 9, Lane 170, Sec. 1, Shenlin Rd.,
Daya Township, Taichung County 428, Taiwan
Tel: 886-4-2568-1353 Fax: 886-4-2565-4689 E-Mail:samuel.nebox@msa.hinet.net

Specification of Lithium Polymer Rechargeable Battery Pack

Date: Sept. 22, 2008

Model No: HP-8030A

Item	Rated Performance	Remarks
Number of Cell	7	Assembled in Series
Cell Capacity	3.8 Ah	
Lithium Content of Cell	1.14 gram	
Total Pack Lithium Content	7.98 grams	
Total Pack Capacity	3.8 Ah	
Nominal Voltage	26.6 Vdc	
Working Voltage	21.0 ~ 29.4 Vdc	
Max. Charge Voltage	29.4 Vdc	
Min. Discharge Voltage	21.0 Vdc	
Charging Current	≦3.0 A	Constant Current / Constant Voltage
Max. Discharge Current	≦10.0 A	
End of Charge Condition	60. mA	
Operation Temperature	-10℃ ~ 55℃	14°F – 131°F
Storage Temperature	-20℃ ~ 45℃	
Net Weight	1.4 Kgs (3.0 Lbs)	
Dimensions (mm)	191.(L)*121.(W)*62.3(H)	
Overcharge Protection Voltage	4.35±0.01 Vdc	Detecting each cell respectively
Overcharge Release Voltage	4.00±0.01 Vdc	Detecting each cell respectively
Overdischarge Protection Voltage	2.50±0.01 Vdc	Detecting each cell respectively
Overdischarge Release Voltage	3.00±0.01 Vdc	Detecting each cell respectively
Overcharge Balancing Current	39. mA	
Short Circuit Protection	Yes	
Pin Designation of Connector	Pin 1: Common Ground; Pin 2: B(+); Pin 3: Ch(+)	

Note:

B(+) means "Positive" of battery, and Ch(+) indicates "Positive' of charger.

Samuel Wang
Marketing Vice President
HERS Precise Products Inc.

HERS Precise Products Inc.

**Address: No.10, Alley 9, Lane 170, Sec. 1, Shenlin Rd.,
Daya Township, Taichung County 428, Taiwan**
Tel: 886-4-2568-1353 Fax: 886-4-2565-4689 E-Mail:samuel.nebox@msa.hinet.net

Compliance Declaration of Lithium Polymer Rechargeable Battery Pack

Date: Sept. 22, 2008

According to the 48th Edition of the IATA Dangerous Goods Regulations effective January 2007, all lithium ion and/or lithium polymer cells and batteries must be tested in accordance with the "UN Manual of Tests and Criteria, Part III, Subsection 38.3 (Test T1-T8), November 1, 2006".
Hereafter we, HERS Precise Products Inc., certify that the model(s) listed in this document is complied with the requirements from test T1 through test T8, specified on "UN Manual of Tests and Criteria, Part III, Subsection 38.3".

Lithium Polymer Rechargeable Battery Manufacturer:	HERS Precise Products Inc.
Lithium Polymer Rechargeable Battery Model(s):	HP-8030A

No.	Test Items	Results	
T1	Altitude Simulation	Yes Pass	□Fail
T2	Thermal Test	Yes Pass	□Fail
T3	Vibration	Yes Pass	□Fail
T4	Shock	Yes Pass	□Fail
T5	External Short Circuit	Yes Pass	□Fail
T6	Impact (For cell only)	--------	--------
T7	Overcharge (For battery only)	Yes Pass	□Fail
T8	Forced Discharge (For cell only)	--------	--------

Samuel Wang
Marketing Vice President
HERS Precise Products Inc.