10.0 510(k) Summary

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:	March 21, 2006
10.6	Trade/Proprietary Name:	OxLife Freedom Five™ Oxygen Concentrators
10.7	Common/Usual Name:	Oxygen Concentrator
10.8	Classification Name:	Portable Oxygen Concentrator

10.9 Comparison to Currently Marketed Devices:

The modified OxLife Oxygen Concentrator is substantially equivalent to the existing OxLife Oxygen Concentrator (K971964 & K933081)

10.10 Device Description:

The OxLife Oxygen Concentrators are prescription devices designed to provide an inexpensive supply of supplemental oxygen in a home, automobile or institution without a continuous source of purified oxygen. They are not life-supporting nor life-sustaining devices. The devices operate through the use of molecular sieve material that binds with the water and nitrogen in filtered room air to leave a gas that is approximately 93% oxygen when delivered to the patient. The compressor creates a vacuum to suck room air through a pre-filter and HEPA filter into a holding tank. At the same time, downstream of the compressor, the air from the previous cycle is pressurized into one of the two aluminum welded molecular sieve tanks. As the oxygen is forced out of the end of the tank, it enters a "T" fitting that directs most of the gas to flush the nitrogen out of the second molecular sieve tank into the ambient air. The remaining oxygen is delivered to the patient. On the next cycle, the air is directed into the second molecular sieve tank with the oxygen generated flushing the first tank and continuing the supply to the patient. This repetitive cycle generates the oxygen

510(k) Summary page two

necessary to flush and prepare the saturated sieve tank while supplying the patient with a continuous flow of high concentration oxygen.

All models have inverter capability to use a 12 Volt DC power as well as 110v.

10.11 Indications for Use:

The OxLife oxygen concentrators are intended to provide supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

10.12 Technological Characteristics:

The OxLife oxygen concentrator operates by using molecular sieve material to absorb water and nitrogen from filtered air. The resulting gas has an increased concentration of oxygen. This technology is well established and has been used in the predicate device as well as other legally marketed products. These modifications have not affected the technological characteristics of the device.

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 modified OxLife Oxygen Concentrators are substantially equivalent to the currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2006

Ms. Margaret K. Poteat
Genera Manager/Management Representative
Oxlife Limited Liability Company
141 Twin Springs Road
Hendersonville, North California 28792

Re: K060922
Trade/Device Name: Oxlife Freedom Five Oxygen Concentrators
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: May 18, 2006
Received: May 19, 2006

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.

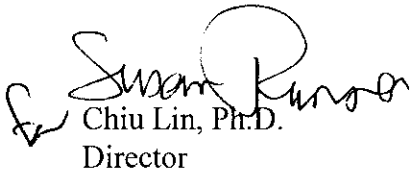
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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) 276-0120. 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

APPENDIX D

Indications for Use

510(k) Number: K060922

Device Name: Oxlife Freedom Five Oxygen Concentrators

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

Prescription Use √ 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: K060922