9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

"510(k) SUMMARY" K971964

9.1 Trade/Proprietary Name: OxLife Excell™ Oxygen Concentrators

9.2 Common/Usual Name: Oxygen Concentrator

AUG 15 1997

9.3 Classification Name: Portable Oxygen Generator

9.4 Comparison to Currently Marketed Devices

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

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

The major change to the device has been the reduction in the size of the molecular sieve tanks and subsequent volume of sieve material. This change allowed the elimination of the crossover valve and required a reduction of the cycle time.

A separate change to be implemented is the addition of an optional, larger inverter capable of operating the 6 LPM models using 12 Volt DC power. Currently, these models are specifically excluded from 12 volt use due to their large power draw.

9.6 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.

9.7 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.

9.8 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 new inverter provides adequate power to run the larger 6 LPM devices from a 12 Volt DC power source.

9.9 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 20856

Ms. Regina K. Ogdon
OxLife, Inc.
917 - 919 S.E. 15th Avenue
Cape Coral, Florida 33990

AUG 15 1997

Re: K971964
OxLife Excell™ Oxygen Concentrators
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: May 21, 1997
Received: May 28, 1997

Dear Ms. Ogdon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) File Number: K971964

Device Name: OxLife Excell Oxygen Concentrators

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

Chad Whitmore for AAC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971964

prescription use ✓