9.0 SUMMARY OF SAFETY AND EFFECTIVENESS

K955549

"510(k) SUMMARY"

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9.1 Trade/Proprietary Name: OxLife Oxygen Concentrators

9.2 Common/Usual Name: Oxygen Concentrator

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

9.5.1 Discussion

The OxLife Oxygen Concentrators are prescription devices designed to provide an inexpensive supply of supplemental oxygen in a home or institution without a continuous source of purified oxygen. They are not life-supporting or life-sustaining devices. The device works by filtering room air into a holding tank. The air is then flushed through two aluminum welded molecular sieve tanks in series. The molecular sieve material absorbs nitrogen which comprises approximately 78% of the makeup of the room air. The resulting gas is approximately 93% oxygen.

This modification is designed to increase the output of the device to enable an oxygen flow of up to 6 LPM at 93% ± 3% purity. The device will be marketed with several options to provide the most marketing flexibility. One set of devices will be marketed with a single oxygen outlet through a single flow meter. The others will be marketed with two oxygen outlets, each with it's own regulator and flow meter. The single outlet devices will be sold with a 5 LPM (L-5) model or 6 LPM (L-6) model with a 5 LPM or 6 LPM flow meter respectively. The dual outlet device (DL-3) will be marketed with two 6 LPM flow meters. This device is designed to provide for the needs of two patients in any combination of flows up to 6 LPM. The major change to the device has been the replacement of the single-headed Thomas WOB-L compressor with a dual-headed Thomas WOB-L compressor. This doubled the output to 3 CFM, facilitating the increased oxygen flow.

9.5.2 Physical Specifications

9.5.2.1 Modified components

There are two components that have been changed to accomplish this modification. The compressor has been upgraded to a dual-headed Thomas compressor, as discussed above, and the circuit breaker has been increased to a 5 AMP breaker from a 4 AMP breaker to accommodate the increased power requirements of the new compressor.

9.5.2.2 Modified materials

None of the air or oxygen contact materials have been modified.

9.5.2.3 Modified physical specifications

The only physical specification that has changed is the overall weight of the unit. The new compressor adds 6 pounds, increasing the unit weight to 43 pounds.

9.5.3 Operational Specifications

9.5.3.1 Flow Rates

The liter flow of oxygen has been increased to a maximum of 6 LPM from 4 LPM. The outlet pressure remains at 5 PSI.

9.5.3.2 Accuracy

The accuracy of the oxygen concentration remains the same at 93% ± 3% for flow rates greater than 2 LPM.

9.5.3.3 Environmental Susceptibility

The modifications do not have any effect on the susceptibility of the unit to withstand environmental influences. The ability of the unit to perform within specifications under normal temperature and pressure variations and it's ability to withstand electrostatic discharge (ESD) and Electromagnetic interference (EMI) has not changed.

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 the 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.

9.8 Conclusion

Based on the design, performance specifications and intended use, the modified OxLife Oxygen Concentrators are substantially equivalent to the currently marketed devices.