NOV - 3 1999

K991722

6.0 510(k) Summary

Submitter's Name: Greg Clites

Address: Sunrise Medical HHG Inc
Respiratory Products Division
100 DeVilbiss Drive
P.O. Box 635
Somerset, PA 15501-0635

Phone #: 814-443-7441

Fax #: 814-443-7571

Contact Person: Greg Clites

Date Summary Prepared: May 14, 1999

Name of Device: DeVilbiss 5 Liter Oxygen Concentrator

Common Name: Oxygen Concentrator

Classification Name: Portable Oxygen Generator

Legally Marketed Device to which Equivalence is Claimed: DeVilbiss 5 Liter Oxygen Concentrator*

Manufacturer: Sunrise Medical HHG Inc
Respiratory Products Division
100 DeVilbiss Drive
P.O. Box 635
Somerset, PA 15501-0635

Predicate Device 510(k) Number: K953815

* The original FDA 510(k) submittal name for the predicate device was the "5 LPM Oxygen Concentrator".

Device Description:

The *revised* DeVilbiss 5 Liter Oxygen Concentrator is a 1-5 lpm, pressure swing adsorption, oxygen concentrator based on molecular sieve technology. Room air is drawn into the concentrator via a piston style compressor. The air then passes through a series of filters that remove dust, bacteria, and other particulates. A pneumatic valve directs air into one of the two sieve beds. Nitrogen is adsorbed in the bed as the pressure increases while oxygen flows through, thereby producing an enriched oxygen product for the patient. Simultaneously in the other bed, nitrogen is desorbed as the pressure decreases and is exhausted into the atmosphere. A momentary intermediate pneumatic sequence ties the beds together with the exhaust blocked for an enhanced nitrogen purge. The cycle continues, providing a continuous flow of oxygen at a purity of 93% +/-3% to the patient. The concentrator is available with or without an oxygen monitoring device.

Intended Use of the Device:

The *revised* DeVilbiss 5 Liter Oxygen Concentrator is designed to provide supplemental low flow oxygen therapy for patients suffering from COPD, cardiovascular disease, and lung disorders. The oxygen concentrator is used in home type environments: homes, nursing homes, patient care facilities, etc.

Technological Characteristics:

The key technological characteristic differences between the *revised* DeVilbiss 5 Liter Oxygen Concentrator and the *predicate* DeVilbiss 5 Liter Oxygen Concentrator are summarized below:

The operating principle of the single pneumatic valve *revised* DeVilbiss 5 Liter Oxygen Concentrator is the same as the dual pneumatic valve *predicate* DeVilbiss 5 Liter Oxygen Concentrator, with the exception that the *revised* concentrator operates with a timed cycle and the *predicate* concentrator cycles based on the monitoring of system pressure. Operating principle:

Room air is drawn into the pressure swing adsorption molecular sieve technology oxygen concentrator by a compressor. Exiting the compressor, the air enters a four-way directional valve and is directed into one of two cylinders containing molecular sieve material. Nitrogen is adsorbed in the bed being pressurized, while oxygen flows through, thereby producing an enriched oxygen product for the patient. The other bed is simultaneously being depressurized, cleansing the bed of nitrogen. The process is alternated between the two beds assuring the patient a continuous supply of oxygen. The additional predicate concentrator valve serves to enhance the nitrogen purge with the UOP 5A-MG molecular sieve material to meet the required performance specification. The revised concentrator accomplishes this enhanced nitrogen purge of UOP Oxysiv-5 molecular sieve material via a momentary intermediate valve position, enabling the revised concentrator to meet the required performance specification. Both UOP 5A-MG and Oxysiv-5 are non-hazardous and non-toxic.

The *predicate* DeVilbiss 5 Liter Oxygen Concentrator cycles based on a fixed pressure setting detected in the oxygen accumulator tank. When a pc board mounted pressure transducer detects the set pressure in the accumulator tank, the microprocessor shifts the pneumatic valving. The *revised* concentrator cycles based on a fixed cycle time. The microprocessor shifts the pneumatic valving according to this fixed time.

While the method of shifting the valve to cycle the system is different, the operating principle of the pressure swing adsorption concentrator is the same for both the *revised* DeVilbiss 5 Liter Oxygen Concentrator and the *predicate* device. The oxygen purity requirement to the patient is satisfied for both products, hence there is no effect on safety and effectiveness.

The *revised* and *predicate* concentrator electronics have been designed with the same microprocessor. Since the functionality of the electronics has been modified for the *revised* concentrator with implementation of the timed cycle and an accompanying decrease in alarms, the programming of the processor is different. With the exception of the No Power and the Low Pressure alarms, the alarm features (High Pressure, Long Cycle, Short Cycle, and No Flow) have been removed from the *revised* concentrator. New software documentation will be generated accordingly. A high pressure indication is most directly tied to the safety of the patient. This will mechanically be maintained via the use of a pressure relief valve on the *revised* concentrator. The Long and Short Cycle alarms are not necessary on the *revised* concentrator since it is controlled by a fixed cycle time The High Pressure, Long Cycle, and Short Cycle alarms shut the *predicate* concentrator down in the event that one of these conditions was detected by the software, in an effort to protect the concentrator from deterioration, but are not directly tied to the oxygen performance. Hence, the modified software and accompanying reduction in the patient alert alarms from the *revised* DeVilbiss 5 Liter Oxygen Concentrator do not present new issues of concentrator safety or effectiveness.

Performance Data:

The key performance descriptor for the oxygen concentrator devices is the oxygen purity performance at 1-5 lpm of oxygen output. The theoretical maximum oxygen purity which is capable from a molecular sieve concentrator is 95.5%, and the commonly accepted minimum level in the concentrator market is 90%. Based on tests performed, both the *revised* DeVilbiss 5 Liter Oxygen Concentrator and the *predicate* concentrator meet this requirement.

Conclusion: The oxygen purity levels for the *revised* and *predicate* concentrators are equivalent, hence there is no effect on safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV -3 1999

Mr. Greg Clites
Sunrise Medical HHG Inc.
Respiratory Products Division
100 DeVilbiss Drive
P.O. Box 635
Somerset, PA 15501-0635

Re: K991722
DeVilbiss 5 Liter Oxygen Concentrator
Regulatory Class: II (two)
Product Code: 73 CAW
Dated: August 31, 1999
Received: September 1, 1999

Dear Mr. Clites:

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 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). 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/dsma/dsmamain.html".

Sincerely yours,

Ceila M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K991722

Device Name: DeVilbiss 5 Liter Oxygen Concentrator

Indications For Use:

The DeVilbiss 5 Liter Oxygen Concentrator is intended for use as an oxygen concentrator to provide supplemental low flow oxygen therapy in the home, nursing homes, patient care facilities, etc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K991722

Prescription Use x OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)