Section 5.0 510(k) Summary

K081468

Administrative Information and Device Identification

AUG 25 2008

Name and address of the manufacturer and sponsor of the 510(k) submission:		Sunrise Medical 100 Devilbiss Drive Somerset, PA 15501
FDA registration number of the manufacturer of the new device:		2515872
Official contact person for all correspondence:		Joseph E. Olsavsky VP – Global Quality & Regulatory Sunrise Medical 100 DeVilbiss Drive Somerset, PA 15501 Phone: 814-443-7690 Fax: 814-443-7597 Email: joe.olsavsky@devilbisshc.com
Date Prepared:		May 15, 2008
Device Name:		DeVilbiss Portable Oxygen Concentrator System
Proprietary name of new device:		DeVilbiss Portable Oxygen Concentrator System
Common or usual name of the device:		Portable Oxygen Concentrator
DeVilbiss Model Number		Model 306 Series
Classification of the predicate device:		Class II
Classification of new device:		Class II
Classification Panel:		Anesthesiology
Panel Code:		CAW
CFR Regulation Number:		21 CFR 868.5440
Predicate Device Name(s) and 510(k) number(s):		Sequal Eclipse Portable Oxygen Concentrator - K013931

Description of Device:

The model 306 Series oxygen concentrator system is a device that produces an oxygen enriched gas mixture by drawing in room air and extracting nitrogen, thus allowing oxygen to be delivered at a range of prescribed flows to patients with low oxygen saturation levels in the blood. The 306 Series is light weight and can operate on an external battery pack, features which allow the 306 Series to be readily transported by the patient. It has two operating modes: continuous product flow at up to 3 LPM and pulse dosage mode at settings of 1 to 6. In pulse dosage mode, the concentrator delivers a bolus of oxygen at each inhalation in an amount equal to 14cc times the setting value.

Comparison of Device Technological Characteristics to Predicate Device:

This device has similar technological characteristics as the predicate device. The DeVilbiss Portable Oxygen Concentrator is equivalent in functional characteristics to the existing legally marketed predicate device. The device generates no less then 91% +/- 3% enriched gaseous oxygen concentration by drawing in room air and extracting nitrogen. Both devices are tested and approved to recognized safety standards. No new technologies have been introduced in the DeVilbiss Portable Oxygen Concentrator. See Section 12.0.

Statement of Intended Use:

The DeVilbiss Portable Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring low flow oxygen therapy. The patient typically receives the oxygen through a nasal cannula. The device delivers flow rates between .5 and 6 liters per minute of oxygen over 90% concentration. It is used at a patient's home or for their portable needs outside the home and can also be used in institutions such as nursing homes or sub-acute care facilities. Oxygen concentrators are not considered either life supporting or life sustaining. The device has no contraindications

Non-Clinical Testing:

This device has been tested to appropriate ISO, ASTM, and IEC standards and other applicable requirements passing all test protocols. The DeVilbiss Portable Oxygen Concentrator was designed and tested according to guidance outlined in:

1. FDA's Draft Reviewer Guidance for Premarket Notification Submissions – Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices (November 1993); and
2. FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005),

As suggested by FDA's November 1993 publication entitled "Reviewer Guidance for Premarket Notification Submissions – Anesthesiology and Respiratory Devices Branch; Division of Cardiovascular, Respiratory, and Neurological Devices" the DeVilbiss

Portable Oxygen Concentrator was tested in accordance with the applicable voluntary standards. The DeVilbiss Portable Oxygen Concentrator met the required performance criteria and functioned as intended.

See Section 16.8, Section 17.0, Section 18.0 and Attachment B.

Statement of Safety and Effectiveness:

Analysis of comparison of design, function and features of the DeVilbiss Portable Oxygen Concentrator System to the Sequal Eclipse (K013931), together with the results of testing demonstrates the device to be substantially equivalent to the predicate device in terms of meeting performance criteria and functioning as intended.

Conclusion:

The DeVilbiss Portable Oxygen Concentrator System is substantially equivalent to the predicate device listed in this Summary and the device, as changed, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2008

Mr. Joseph E. Olsavsky
Vice President Global Quality and Regulatory
Sunrise Medical
DeVilbiss Healthcare
100 DeVilbiss Drive
Somerset, Pennsylvania 15501

Re: K081468
Trade/Device Name: DeVilbiss Portable Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: May 22, 2008
Received: May 27, 2008

Dear Mr. Olsavsky:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Indications for Use

510(k) Number: (if known): Not yet assigned

Device Name: DeVilbiss Portable Oxygen Concentrator

Indications For Use:

The Model 306 iGo Portable Oxygen Concentrator System is indicated for the administration of supplemental oxygen. The device is not intended for life support, nor does it provide any patient monitoring capabilities.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K081468