FEB 3 2006

K053240

Section 5.0 510(k) Summary

Administrative Information and Device Identification

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 Director – Regulatory Affairs Sunrise Medical 100 DeVilbiss Drive Somerset, PA 15501 Phone: 814-443-7690 Fax: 814-443-7597 Email: joe.olsavsky@sunmed.com
Date Prepared:		November 17, 2005
Device Name:		Oxygen Cylinder Filling System
Proprietary name of new device:		DeVilbiss Oxygen Cylinder Filling System
Common or usual name of the device:		Oxygen Cylinder Filling System
DeVilbiss Model Number		Model 535 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):		*CHAD Therapeutics Total O2 Delivery System* **(K013472)** *CHAD Therapeutics Total O2 Delivery System* **(K971889)**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Sunrise Medical
Mr. Joseph E. Olsavsky
Director Regulatory Affairs
Respiratory Products Division
100 DeVilbiss Drive
Somerset, Pennsylvania 15501-2125

Re: K053240
Trade/Device Name: DeVilbiss Oxygen Cylinder Filling Systems
Regulation Number: 868.5440
Regulation Name: Portable oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: November 17, 2005
Received: November 18, 2005

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 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

Indications for Use

510(k) Number: (if known): K053240

Device Name: DeVilbiss Model 535D Oxygen Cylinder Filling System

Indications For Use:

The Model 535D Oxygen Cylinder Filling System is intended for use in supplying pressurized oxygen to fill oxygen cylinders for patients' ambulatory use. The device is intended to provide 93% (± 3%) oxygen. This device can be used in homes, nursing homes, patient care facilities, etc.

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: K053240