K020329

SUNRISE

JUN 1 9 2002

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Respiratory Products Division
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510(k) Summary

Submitter's Name: Brian Hershey

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Phone #: 814-443-7577

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Contact Person: Brian Hershey

Date Summary Prepared: April 22, 2002

Name of Device: DeVilbiss PD1000

Common Name: Oxygen Conserver

Classification Name: VENTILATOR, NON-CONTINUOUS (RESPIRATOR)

Legally Marketed Device to which Equivalence is Claimed: DeVilbiss EX2000 Pulse Dose

Manufacturer: Sunrise Medical HHG, Inc. Respiratory Products Division

Predicate Device 510(k) Number: K961126

Device Description:

The DeVilbiss PD1000 compact conserving device is designed to extend the use time of oxygen cylinders. The device uses PulseDose technology to accomplish the oxygen savings. PulseDose senses the start of inhalation and instantly releases a short "pulsed" dose at the very beginning of the inhalation cycle. Since all of the "pulsed" oxygen finds its way deep into the lungs, less oxygen is required to accomplish the same effect than with traditional continuous flow oxygen systems.

The PD1000 compact conserving device contains an integral pressure regulator with CGA 870 style yoke. The pressure regulator reduces the cylinder pressure to 19 – 25 psig. The PD1000 then delivers oxygen to the

patient by sensing inhalation via a pressure switch and opening a two-way valve for a specified period of time controlled by a microprocessor. The unit is designed to deliver 16.5 cc/lpm of oxygen to the patient at 1.0, 1.5, 2.0, 2.5, 3.0, 4.0, 5.0 and 6.0 flow settings. The unit is powered by two "AA" alkaline or nickel metal hydride batteries. The PD1000 has a continuous flow back-up mode that will deliver 2 lpm continuous to the patient in the event of a device failure or dead batteries.

The device has two LED's that indicate battery status and valve activation. When the unit is first turned on, either a red or green LED will flash to indicate the unit is turned on and the battery status. Each time the valve is activated during an inhalation, the red or green LED will flash to indicate the valve was activated and the battery status. The device will operate approximately 4 – 8 hours when the red LED first begins to flash. When the battery voltage drops below approximately 1.9 vdc the red LED will remain on continuously and the valve will no longer operate. The continuous flow back-up mode can still be used to provide oxygen therapy to the patient when the batteries are no longer able to operate the unit.

The ability of the PD1000 to detect patient inspirations is based on the sensitivity of the pressure switch which is set within a range of .1 to .25 cm H2O. The device is capable of delivering a bolus of oxygen at the beginning of each inhalation up to 40 breaths per minute (every 1.5 seconds). This 1.5 second minimum delay between breaths will cause the device to "skip" breaths at rates greater than 40 breaths per minute.

Intended Use of the Device:

The DeVilbiss PD1000 Compact Conserving Device is intended as a delivery device for medical-grade oxygen from high-pressure oxygen cylinders. This is an ambulatory device, which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder.

Technological Characteristics:

The DeVilbiss PD1000 Compact Conserving Device has three key technological characteristic differences as compared to the predicate DeVilbiss EX2000 PulseDose Conserver.

A. Timing

The PD1000 Compact Conserving Device has standard fixed valve times that are programmed into the microprocessor during assembly. This is different from the EX2000 PulseDose conserver in that the valve timing is adjusted during assembly through calibration of the pulse volumes at each dose setting.

Although the valve open timing is set differently between the units, they provide comparable pulse volumes.

There is no effect on safety and effectiveness.

B. Breath Detection

The PD1000 Compact Conserving Device utilizes a pressure switch to detect patient inhalation. This is different from the EX2000 PulseDose conserver which uses a pressure transducer to sense the patient inhalation. Both types of sensors provide adequate sensitivity to detect .1 to .25 cm of H2O vacuum. The pressure switch was selected for the PD1000 in order to reduce the amount of electronics required and gain a more robust sensor.

There is no effect on safety and effectiveness.

C. Alarms

The PD1000 Compact Conserving Device does not have audible alarms unlike the EX2000 PulseDose conserver. The PD1000 operates like the predicate mechanical conservers that are noted in the table of

comparisons. The device is designed for ambulatory use, allowing patients to ambulate longer than they would with a continuous flow regulator on the same cylinder.

There is no effect on safety and effectiveness

Performance Data:

The pulse volumes of the PD1000 were compared to the pulse volumes of the EX2000 predicate device. The pulse volume in cubic centimeters, valve "ON" time and waveform of the pulse volume or "bolus" was recorded for each setting of the PD1000. This data was also obtained for the same settings on the EX2000.

The data indicates that the PD1000 pulse volumes match the corresponding pulse volumes of the EX2000.

See appendix section D.1 for EX2000 / PD1000 Pulse volume comparisons.

Clinical Performance Data:

The DeVilbiss PD1000 Compact Conserving Device contains no new technologies, intended uses or new features that require clinical performance evaluations.

Conclusions:

The non-clinical test data concludes that the units are equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 9 2002

Sunrise Medical HHG, Inc.
c/o Mr. Brian Hershey
Respiratory Products Division
100 DeVilbiss Drive
P.O. Box 635
Somerset, PA 15501

Re: K020329
DeVilbiss PD1000
Regulation Number: 868.5905
Regulation Name: Ventilator, Non-continuous
Regulatory Class: II (two)
Product Code: NFB
Dated: April 22, 2002
Received: April 24, 2002

Dear Mr. Hershey:

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.

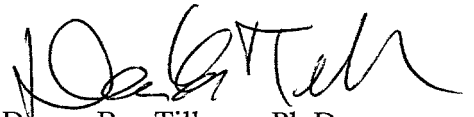
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020329

Device Name: DeVilbiss PD1000

Indications For Use:

The DeVilbiss PD1000 Compact Conserver is intended as a delivery device for medial-grade oxygen from high-pressure oxygen cylinders. This is an ambulatory device, which allows patients to ambulate longer than they would with a continuous flow regulator on the same cylinder.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K020329

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)