JUL 21 2004

K041568

TAB 10

510(K) SUMMARY

Official Contact

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Proprietary Name EOCD

Common/Usual Name Electronic Oxygen Conserving Device (EOCD)

Classification Name Noncontinuous ventilator (IPPB).

Predicate Devices DeVilbiss Model PD 1000(K020329)

Device Description

The EOCD is a pulse dose delivery device for medical-grade oxygen from portable high-pressure oxygen cylinders. Adult patients requiring supplemental oxygen and using ambulatory oxygen can use the EOCD to extend the use time of a fixed volume oxygen source. The device does not provide alarms and is not intended as life support. The device includes a built in regulator, valve, control circuitry, and enclosure. The device will be designed to attach to a standard compressed gas cylinder with a CGA 870 style yoke.

The principle of operation for the EOCD is as follows:

> The EOCD is a device that extends the "use time" from a supply of oxygen. As opposed to continuous delivery of oxygen, the EOCD delivers oxygen only when needed and provides a nominal oxygen conservation ratio of 4 to 1. The EOCD senses inspiration and opens a valve for a short duration of time. When the valve is open, oxygen flows to the patient. The duration the valve is opened is based on the flow setting. The patient can select the continuous mode of operation by manually selecting a continuous flow setting on the rotary switch.

The EOCD provides three modes of operation: conserving (pulse) mode, continuous mode, and off mode.

Indications for Use

The EOCD is intended as a pulse dose delivery device for medical-grade oxygen from portable high-pressure oxygen cylinders. Adult patients requiring supplemental oxygen and using ambulatory oxygen can use the EOCD to extend the use time of a fixed volume oxygen source.

This device does not provide alarms and is not intended as life support.

Technological characteristics, comparison to predicate devices

The Respironics EOCD has the same operating principles and same technology as the predicate device. The difference is that the EOCD conserve ratio is 4:1 compared to the predicate 3:1. However, there is no effect on safety or effectiveness.

Performance testing

Performance, environmental, electrical, mechanical and electromagnetic compatibility testing was performed to prove the safety and effectiveness of the EOCD.

Conclusion

It is the conclusion of Respironics that the EOCD is substantially equivalent to devices already on the market (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2004

Ms. Lou Anne Kinney
Director, Regulatory Affairs & Clinical Affairs
Respironics, Incorporated
Homecare Division
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668-8550

Re: K041568
Trade/Device Name: EOCD
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: June 4, 2004
Received: June 10, 2004

Dear Ms. Kinney:

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 (301) 594-4646. 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/dsma/dsmamain.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): K041568

Device Name: EOCD

Indications for Use:

The EOCD is intended as a pulse dose delivery device for medical-grade oxygen from portable high-pressure oxygen cylinders. Adult patients requiring supplemental oxygen and using ambulatory oxygen can use the EOCD to extend the use time of a fixed volume oxygen source.

This device does not provide alarms and is not intended as life support.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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: K041568