TAB 10

K050414

510(K) SUMMARY

Official Contact

Zita Yurko
Manager, Regulatory Affairs
Respironics Inc.
1001 Murry Ridge Lane
Murrysville, PA 15668

Phone: 724-387-4120
Fax: 724-387-4216
zita.yurko@respironics.com

Proprietary Name PLOX

Common/Usual Name Portable Liquid Oxygen System

Classification Name Portable liquid oxygen unit. (BYJ).

Predicate Devices Puritan-Bennett Helios Portable Liquid Oxygen System (K993220)

Device Description

The PLOX is a double walled vacuum insulated cryogenic vessel designed to hold approximately 1 pound of liquid oxygen at a pressure of 22 psig with heat exchange tubing, relief valves and a pneumatic conserving device housed in a plastic enclosure. Oxygen is stored under low pressure in its liquid state where the pressure is limited by the pressure relief valve. The liquid oxygen is converted to near ambient temperature gaseous oxygen through a system of tubes and warming coils for delivery to patients requiring supplemental oxygen by a single lumen cannula. The PLOX is a mechanical device and does not contain any electronics or software. The PLOX is designed to be refilled from industry standard liquid oxygen stationary units already cleared and in the marketplace.

The PLOX provides three modes of operation: conserve mode, continuous mode, and off mode.

Indications for Use

The PLOX is intended to provide supplemental oxygen to patients who have difficulty extracting oxygen from the air that they breathe. The patients would normally receive oxygen via a nasal cannula. It is intended for ambulatory use inside and outside of the home. It is not intended to be life supporting or life sustaining. The device has no contraindications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2005

Respironics, Incorporated
C/O Mr. Ned Devine
Responsible Third Party Official
Intertek ETL SEMKO
3033 Madison Avenue SE
Grand Rapids, Michigan 49548

Re: K050414
Trade/Device Name: Respironics PLOX
Regulation Number: 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: March 25, 2005
Received: March 28, 2005

Dear Mr. Devine:

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.

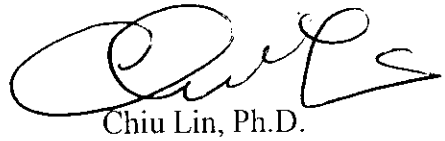
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): _____

Device Name: Respironics PLOX

Indications for Use:

The PLOX is intended to provide supplemental oxygen to patients who have difficulty extracting oxygen from the air that they breathe. The patients would normally receive oxygen via a nasal cannula. It is intended for ambulatory use inside and outside of the home. It is not intended to be life supporting or life sustaining. The device has no contraindications.

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 K050444