

MAR 20 2008

K072723/5<sup>2</sup>  
GoLox

## TAB 5

### 510(K) SUMMARY

**Date of Submission** February 5, 2008

**Official Contact** Zita A. Yurko  
Director Regulatory Affairs  
Respironics, Inc.  
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**Classification Reference** 21 CFR 868.5655

**Product Code** BYJ – Portable Liquid Oxygen Unit

**Common/Usual Name** Portable Liquid Oxygen Unit

**Proprietary Name** Respironics GoLox USP

**Predicate Device(s)** Respironics PLOX (K050414)

**Reason for submission** device modification

### Substantial Equivalence

The GoLox has the following similarities to the previously cleared predicate device:

- Same intended use.
- Same operating principle.
- Same technology.
- Same manufacturing process.

The PLOX was cleared in K050414 for delivering oxygen to patients after being filled with USP 99% oxygen from stationary liquid vessels.

Comprehensive testing was performed to determine equivalence between the GoLox and PLOX (K050414). Testing included connection/disconnection of proprietary connector, purity and flowrates in stated environmental conditions.

## **Intended Use**

The GoLox 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.

## **Device Description**

The GoLox 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 device is not intended as life support or life sustaining. The GoLox USP s designed to be refilled from industry standard liquid oxygen stationary units already cleared and in the marketplace.

*(End of Tab.)*



MAR 20 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Respironics, Incorporated  
C/O Mr. Ned Devine  
Senior Staff Engineer  
Underwriters Laboratories, Incorporated  
333 Pfingsten Road  
Northbrook, Illinois 60062

Re: K072723  
Trade/Device Name: GoLox USP  
Regulation Number: 21 CFR 868.5655  
Regulation Name: Portable Liquid Oxygen Unit  
Regulatory Class: II  
Product Code: BYJ  
Dated: March 7, 2008  
Received: March 11, 2008

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.



Page 2 – Mr. Devine

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9200 Corporate Boulevard  
Rockville MD 20850

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,

A handwritten signature in black ink that reads "Chiu Lin, Ph.D." with a stylized flourish at the end.

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: GoLox USP

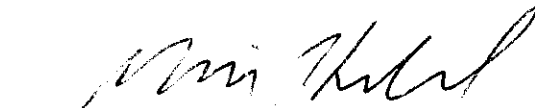
The GoLox USP is intended to provide supplemental oxygen to patients who have difficulty extracting oxygen from the air that they breathe. The patients would normally receive oxygen via a nasal cannula. It is intended for ambulatory use inside and outside of the home. It is not intended to be life supporting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

Prescription Use X AND/OR Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number: K072723