OCT 18 2007

K072050

510(k) Summary
COPD Partners
Model 300P Liquid Oxygen Portable

Submitter Richard J. Kocinski
COPD Partners, Inc.
1061 Main Street - #24
North Huntingdon, PA 15642

Phone: 724-861-5510
FAX: 724-861-5530
e-mail rkocinski@copdpartners.net

Date Prepared	7-19-2007
Device Trade Name	Model 300 P Liquid Oxygen Portable
Common Name	Portable Liquid Oxygen Unit
Classification	868.5655
Product Codes	BYJ
Predicate Device	Spirit 300 510(k) Number: K013251 Manufacturer: Caire Inc., 1800 Sandy Plains Industrial Parkway Marietta, GA 30066.

Intended use

The COPD Partners Model 300P Liquid Oxygen Portable will provide a source of supplemental oxygen for ambulatory home healthcare patients, by vaporizing medical grade liquid oxygen, and then dispensing it to the patient via an integral electronic conserving device. The Model 300P Liquid Oxygen Portable is neither a life-sustaining nor life-supporting device.

Device Description

The COPD Partners' Model 300P is a small, lightweight, liquid oxygen portable unit. The unit consists of a vacuum-insulated cryogenic Dewar, an economizer regulator, electronic printed circuit board (PCB), an oxygen conserving system, and a protective case.

The Dewar has a capacity and capability to store 0.33 liters of liquid oxygen. Dependant on the flow selection setting, the control system either delivers the oxygen to the conserving device or delivers a 2 LPM continuous flow directly to the oxygen outlet. The continuous flow setting is labeled CF on the flow method selector. The conserving

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device has an equivalent setting for 1, 2, 3, 4, and 5 LPM prescriptions. At the various conserving device settings, the outlet oxygen gas is delivered in quick pulses beginning at the start of inhalation.

The device also has a provision to track the patient's breath rate and in the event of an increase in breath rate, will deliver an increased volume of oxygen. There are two levels of increased volume, one at 4 breath per minute (BPM) over normal breath rate and another at 8 BPM over normal breath rate. The device delivers an extra 16 cc at each of these two thresholds. The COPD Partners Model 300P is transfilled from a commercially available medical grade liquid oxygen source.

Technological Characteristics as Compared to the Predicate

The COPD Partners 300P Liquid Oxygen portable is mechanically the same as the Caire Spirit 300 portable oxygen system. As such, the user interface and physical attributes are the same.

There are three primary differences:

1. The method of delivering oxygen in the COPD Partners 300P Liquid Oxygen Portable has been optimized to deliver the required volume of 16 cc per L seting at a variable flow rate using two control valves to deliver the best flow rate based upon the patient's current breath rate and prescription setting. The Caire Spirit 300 uses a single control valve (flow) which delivers a fixed volume of 15 cc per L of prescription flow setting.

Additonally, the COPD Partners' Model 300P uses a relatively quick rise in breath rate as an indicator of need. When a rise of > 4 breaths per minute (BPM) in rate is noticed, the unit delivers an additional 16 cc of oxygen per breath, the equivalent to turning the knob up one setting. If the patient's BPM rises > 8 BPM, the conserver adds yet another 16 cc of O_2 per breath. When the user drops below the 4 BPM threshold and returns to normal breathing, the volume is lowered to the normal setting volume. In this way, the device does not stay at a higher O_2 delivery mode, which can happen when patients are adjusting their own settings. In effect, the COPD Partners' conserver attempts to automate an adjustment that is currently being done by the user in a manual process.

The Caire Spirit 300 does not have this capability.

2. The 300P Liquid Oxygen System uses 4 AA batteries for an estimated 300 hours of battery life. The Caire Spirit 300 uses 2 C batteries for and estimated 500 hours of battery life. Since both systems have a low battery warning indicator and allow the patient to switch to a manual 2 LPM continuous flow setting if batteries are depleted, there is no change in safety of effectiveness of the COPD Partners 300P Liquid Oxygen Portable vs.

the Caire Spirit 300 Portable.

3. The COPD Partners model 300P does not have a 1.5 LPM flow rate setting. The bench testing for the revised conserver algorithm indicate the new algorithm is capable of covering this flow rate. No new patient safety issues have been identified

Summary of Testing

Verification and Validation testing has been completed using the COPD Partners Model 300P Liquid Oxygen Portable to assure that the device meets the safety and performance requirements described in the specifications. This testing includes:

1. Bench testing to verify that:
   a. Oxygen purity levels in the product specification are met.
   b. Safety mitigations as identified in the Model 300P risk assessment have been completed
   c. Oxygen delivery rate settings as defined in the product specification are met
2. Independent testing and evaluation to verify that the Model 300P Liquid Oxygen Portable meets the requirements of:
   a. UL 60601-1-1:2005 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical system
   b. IEC 60601-1-2:2001 and A1-2004 Medical electrical equipment - Part 1-2 : General requirements for safety - Section 2: Collateral standard: Electromagnetic compatibility - Requirements and tests.

All results of tests met the acceptance criteria. Testing demonstrates that the COPD Partners Model 300P Liquid Oxygen Portable performs at least as well and is as safe and as effective as the predicate Caire 300.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

COPD Partners, Incorporated
Mr. Paul Dryden
Consultant
ProMedic, Incorporated
3460 Pointe Creek Court, # 102
Bonita Springs, Florida 34134-2015

Re: K072011
Trade/Device Name: Model 300P Liquid Oxygen Portable
Regulation Number: 21 CFR 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: July 19, 2007
Received: July 23, 2007

Dear Mr. Dryden:

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.

Food and Drug Administration
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) 276-0115. 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): K072011

Device Name: Model 300P Liquid Oxygen Portable

Indications for Use:

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Prescription Use _XX__ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K072011