K071461

**Non Confidential 510(k) Summary**
**Page 1 of 3**
**COPD Partners**
**Model 300 D Home Oxygen Liquefier**

| | |
|---|---|
| **Date:** | August 17, 2007 |
| **Submitter:** | Richard J. Kocinski<br>VP of Product Development<br>COPD Partners, Inc.<br>1061 Main Street - #24<br>North Huntingdon, PA 15642<br>Phone: 724-861-5510 |
| **Device Trade Name** | Model 300 D Liquefier |
| **Common Name** | Accessory to Oxygen Concentrator and Liquid Oxygen Portable |
| **Classification** | 868.5440/868.5655 |
| **Product Codes** | CAW/BJY |
| **Predicate Device** | In-X Corporation Home-Away System Model 1041 (K042944)<br>Caire Spirit 300 HAS (K050153) |

AUG 2 1 2007

**Device Description**

The COPD Partners' model 300D is a home oxygen liquefaction device. The product is intended to connect to an oxygen concentrator that is equipped with an oxygen sensing device to assure adequate levels of oxygen purity. The model 300D then splits the gas source from the concentrator, giving the patient their desired level of gas flow and uses the remaining flow for the liquefaction portion of the unit. The liquefaction portion of the device consists of desiccants, a boost pump compressor, a high pressure compressor, a series of heat exchangers, a dual stage cascade refrigeration pre-cooler, a microcontroller based controller system, and a Dewar with a Joule Thompson (JT) valve. This device pressurizes the gas, cools it, and then expands the gas through the JT valve, where a portion of the gas will convert to liquid. This liquid oxygen will be used to fill a liquid oxygen portable such as the COPD Partners' Model 300P. The device indicates the level of liquid in the Dewar and has a control system to display this information to the user. In addition, it automatically turns on to maintain a desired level of liquid in the Dewar.

## Indications for Use

The Model 300D Home Oxygen Liquefier is intended for use in liquefying oxygen supplied by a concentrator equipped with an oxygen sensing device. The concentrator used with the home oxygen liquefier should generate >90% oxygen purity nominally, and alert the user if this purity drops to unacceptable levels. This liquid oxygen is intended for use with the liquid portable products rated for 93% oxygen such as the Caire Spirit 300 HAS product. This system and the associated portable are intended for use with 93% (±3%) oxygen.

It may be used in the home or institution. It is intended to be used with both pediatric and adult patients. It is not intended to be a life sustaining or life supporting device. The device has no contraindications.

## Environment of use

Home or institution.

## Device Attributes

| | |
|---|---|
| Liquefaction rate | 0.16L $_{Lox}$/Hr (after cool down) |
| Input Voltage and Current | 120 VAC (±10%) 60 HZ , 12 A |
| Average Power Consumption | 950 Watts |
| Input Oxygen Purity Required | >85% |
| Input Oxygen Pressure | 5 to 10 psig |
| Weight | 180 Lbs $^{\pm}$ 5 Lbs |
| Storage and Transport Temperature | -20 to 50 °C |
| Operating Temperature | + 5 to 40 °C |
| Operating Humidity | 15 to 95% R. H., Non-Condensing |

## Technological Characteristics as Compared to the Predicate

The COPD Partners Model 300D Home Oxygen liquefier is substantially equivalent to the In-X Home–Away System, Model 1041 cleared under K042944. Both systems are compatible with oxygen concentrators that deliver ≥ 5L/min USP Oxygen at a rated 93% USP O2 purity, and a minimum of 87% purity. Both systems are compatible with bottom fill type LOX portable units manufactured by their respective companies. Both have been tested to meet standards for medical device safety, EMC compatibility, liquid oxygen production rates, mechanical shock and vibration.

The primary difference between the COPD Partners Model 300 D Home Oxygen Liquefier and the In-X Model 1041 Home-Away system is the method of liquefaction of the oxygen. The COPD Partners Model 300 uses standard two stage refrigeration process with a separate refrigeration system and Joule-Thompson valve and a Joule Thompson valve integral to the Dewar assembly. The In-X System uses a Sterling Cycle liquefaction system with an integral cooler and Dewar Assembly.

This difference does not affect the safety or effectiveness of the COPD Partners Model 300D Home Oxygen Liquefier

## Summary of Testing

Verification and Validation testing has been completed on the COPD Partners Model 300D Liquefier 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. The liquefaction rates and Oxygen purity levels in the product specification are met.

    b. Safety mitigations as identified in the Model 300D risk assessment have been completed.

2. Independent testing and evaluation to verify that the Model 300 D Liquefier meets the requirements of:

    **a. UL 60601-1-1:2006 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical system.**

    **b. IEC 60601-1-2:2007 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.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

COPD Partners, Incorporated
C/O Mr. Paul E. Dryden
President
Promedic, Incorporated
3460 Pointe Creek Court, Suite 102
Bonita Springs, Florida 34134-2015

AUG 21 2007

Re: K071461
Trade/Device Name: Model 300D Home Oxygen Liquefier
Regulation Number: 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: CAW, BYJ
Dated: May 23, 2007
Received: May 25, 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.

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 Statement



**510(k) Number:** K071461 (To be assigned)

**Device Name:** Model 300D Home Oxygen Liquefier

**Indications for Use:**

The Model 300D Home Oxygen Liquefier is intended for use in liquefying oxygen supplied by a concentrator equipped with an oxygen sensing device. The concentrator used with the home oxygen liquefier should generate >90% oxygen purity nominally, and alert the user if this purity drops to unacceptable levels. This liquid oxygen is intended for use with the liquid portable products rated for 93% oxygen such as the Caire Spirit 300 HAS product. This system and the associated portable are intended for use with 93% (±3%) oxygen.

**Prescription Use XX** (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 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: K071461