K091191

TAB 5

510(K) SUMMARY

Date of Submission	April 20, 2008
Official Contact	Zita A. Yurko Director, Regulatory Affairs Respironics, Inc. 1001 Murry Ridge Lane Murrysville, PA 15668 Zita.yurko@respironics.com 724-387-4120 t 724-882-4120 c 724-387-7490 f
Classification Reference	21 CFR 868.5440
Product Code	CAW – Portable oxygen generator
Common/Usual Name	Portable Oxygen generator
Proprietary Name	Gas Transfill
Predicate Device(s)	Invacare Corp. Home Fill II (K003939) Chad Therapeutics Total O2 (K013472) DelVilbiss Healthcare iFill (K053240)
Reason for submission	new device

OCT 23 2009

Substantial Equivalence

The Gas Transfill is similar to the previously cleared predicate devices in:

- Intended use – to produce and fill medical oxygen cylinders with high pressure gaseous oxygen
- Operating principle - produce high pressure oxygen from gaseous oxygen provided by an external Oxygen Concentrator.

Intended Use

The intended use of the Gas Transfill System is to provide supplemental oxygen to patients and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended to be life supporting nor life sustaining.

Device Description

The Respironics Gas Transfill System is comprised of a high pressure oxygen compressor and an external oxygen concentrator. The oxygen concentrator provides up to 2LPM of gaseous oxygen to the high pressure oxygen compressor for filling medical oxygen cylinders. In addition, the external oxygen concentrator provides up to 3LPM of gaseous oxygen for patient breathing. The external oxygen concentrator can be one of the Respironics series of FDA cleared devices or other manufacturers FDA cleared oxygen concentrators. The patient cannot breathe directly from the high pressure oxygen compressor. The purpose of the high pressure oxygen compressor is to fill medical oxygen cylinders only.

(End of Tab.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 23 2009

Ms. Zita A. Yurko
Director of Regulatory Affairs
Respironics, Incorporated
Sleep & Home Respiratory Group
1001 Murry Ridge Lane
Murrysville, Pennsylvania 15668

Re: K091191
Trade/Device Name: Gas Transfill
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: August 24, 2009
Received: August 25, 2009

Dear Ms. Yurko:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Division 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: Gas Transfill

The intended use of the Gas Transfill System is to provide supplemental oxygen to patients and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use.

The device is not intended to be life supporting nor life sustaining.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L. Schuttes

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

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