K050153

APR 15 2005

510(k) Summary

Submitter:	Caire, Inc 1800 Sandy Plains Industrial Parkway Suite 316 Marietta, GA 30066
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Date Prepared:	December 28, 2004
Device Name:	Spirit 300 HAS
Device Class:	II
Classification Panel:	Anesthesiology
Classification Name:	Portable Liquid Oxygen Unit
CFR Section:	868.5655
Product Code:	BYJ
Predicate Device:	Spirit 300 [FDA 510(k) #K013251]

Device Description:
The Spirit 300 HAS is a small, lightweight, liquid oxygen portable unit. The unit consists of a vacuum-insulated cryogenic dewar, a vaporizer coil, an economizer regulator, two pressure safety relief valves, a manifold, an electronic printed circuit board conserving device and a protective case. The dewar has a capacity and capability to store 0.3 liters of liquid oxygen. The vaporizer coil warms the oxygen gas to a suitable temperature, as it exits the dewar. Dependant on the flow selection setting, the manifold either delivers the gas to the conserving device PCB or delivers a 2 LPM continuous flow directly to the oxygen outlet. The continuous flow setting is labeled CF on the flow selector. The conserving device has equivalent setting for 1, 1.5, 2, 3, 4, and 5 LPM prescriptions. At the various conserving device settings, the outlet gas is delivered in quick pulse dosages just at the onset of patient inhalation. The amount of gas delivered (with each breath) is approximately 15 ml/LPM setting. The Spirit 300 HAS is filled from a concentrator liquefaction device.

Indications For Use:
The CAIRE Spirit 300 HAS will provide a source of supplemental oxygen for ambulatory home healthcare patients, by vaporizing 93% liquid oxygen and then dispensing it to the patient via an integral electronic conserving device. The Spirit 300 HAS is intended to be transfilled only by the In-X Corporation's Home-Away System. The Spirit 300 HAS is neither a life sustaining nor life supporting device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

CAIRA, Incorporated
Mr. Dan Chlan
Quality System / Compliance Manager
BioMedical Division
1800 Sandy Plains Industrial Parkway, Suite 316
Marietta, Georgia 30066

Re: K050153
Trade/Device Name: Spirit 300 HAS
Regulation Number: 868.5655
Regulation Name: Portable Liquid Oxygen Unit
Regulatory Class: II
Product Code: BYJ
Dated: March 21, 2005
Received: March 29, 2005

Dear Mr. Chlan:

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): K050153

Device Name: Spirit 300 HAS

Indications for use: The Spirit 300 HAS will provide a source of supplemental oxygen for ambulatory home healthcare patients, by vaporizing 93% liquid oxygen and then dispensing it to the patient via an integral electronic conserving device. The Spirit 300 HAS is intended to be transfilled only by the In-X Corporation's Home-Away System. The Spirit 300 HAS is neither a life-sustaining nor life-supporting device.

Prescription Use ___X__ (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)

...sion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(k) Number K050153