K033405

OCT 18 2005

Zhejiang Longfei Industrial Co., Ltd.
No. 338 Ningkang West Road, Yueqing, Zhejiang, P.R. China

II. 510(K) Summary

Submitted by:	Zhejiang Longfei Industrial Co., Ltd. No.338, Ningkang West Road, Yueqing 325600, Zhejiang, P.R.China Tel: 0086-21-52661572 Fax: 0086-21-52661040
Contact Person:	Ms. Coco Wang
Date Prepared:	2003-10-08
Proprietary Name:	Longfei LFY-I-5 Oxygen concentrator
Common Name:	Oxygen concentrator
Classification Name:	Portable Oxygen Generator (21 CFR 868.5440)
Predicate Device:	Invacare Platinum 5 Oxygen concentrator 510(k) #K[020386]

Description of the Device:

The Longfei Model LFY-I-5 Oxygen concentrator is an electromechanical, prescription device designed for use in the home, by patients that require supplemental oxygen. Its intended function and use is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Oxygen is delivered to the user by means of standard oxygen supply tubing and a standard nasal cannula, which are not supplied with the device. A standard humidifier bottle may be used, if desired.

The front panel of the device contains the controls and indicators. These include a standard barb fitting for attaching the oxygen tubing, the adjustable flow meter, a power light indicator, an elapsed time meter, and a standard *on/off* rocker type power switch.

Intended Use of the Device:

The LFY-I-5 Oxygen concentrator is a 5-liter per minute oxygen concentrator that is of the pressure swing adsorption (PSA) type. The pneumatic system consists of 5 major components: inlet filtration, air compressor and heat exchanger, synthetic Zeolite molecular sieve beds and

distribution value module, outlet filtration, and flow meter.

The electrical system consists of AC power distribution to the air compressor and a motor with gear reduction used to drive the distribution valve; the unit is double insulated and uses a two-conductor power cable. Device monitoring circuit are included that monitor oxygen concentration. In the event of a malfunction, the unit will shut down and activate visual.

The intended function and use is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Technological Characteristics:

The Longfei LFY-I-5 Oxygen concentrator complies with the ASTM Standard Specifications for Oxygen concentrators for Domiciliary Use (Anesthesia) and the ISO standard 8359: 1996, Oxygen concentrators for Medical Use (Anesthesia). Conformance or variance with these standards is described on the following pages.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2005

Ms. Coco Wang
General Manager
Zhejiang Longfei Industrial Company Limited
Room 1202, No. 28 Building
2288 Caoyang Road
Shanghai,
CHINA 200333

Re: K033405
Trade/Device Name: Model LFY-l-5 Oxygen Concentrators
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: August 1, 2005
Received: August 1, 2005

Dear Ms. Wang:

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.

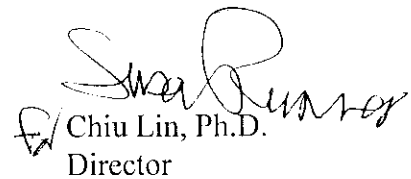
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



/S/ 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: K033405

Device Name: Model LFY-I-5 Oxygen Concentrators

Indications For Use:

The LFY-I-5 Oxygen Concentrators are indicated fro the administration of supplemental oxygen. The device is not intended for life support nor does it provide any patient monitoring capabilities.

Prescription Use ✓ (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)

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

510(k) Number K033405