K102245

510(k) Summary

NOV - 9 2010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: _____.

Submitter:
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Applicant:
Foshan Care Medical Technology Co., Ltd

Address:
No.1 HuaBao South Road, Foshan, Guangdong, China

Date of the summary prepared:
June 15, 2010

Name of the device:
Trade/Proprietary Name: CARE ZY5BA Oxygen Concentrator
Common Name: Oxygen Concentrator

Classification:
Class II as per 21 CFR 868.5440, Portable Oxygen Generator

Legally Marketed Predicate Device:
K071608 A&J-POCA01 Oxygen Concentrator

Intended Use:

The CARE ZY5BA Oxygen Concentrator is intended for use as an oxygen concentrator to provide supplemental low flow oxygen therapy in the home, nursing homes, patient care facilities, etc. The CARE ZY5BA is available by prescription only under the supervision of a physician, and is not intended to support or sustain life.

Description:

The CARE ZY5BA is an AC power electrically operated device. The unit separates oxygen from room air (ambient air), which allows high-purity supplemental oxygen to be delivered through the oxygen outlet, although the concentrator filters the oxygen in a room. It will not affect the normal amount of oxygen in user's room. Air is drawn into the device with a compressor and exposed to molecular sieve adsorbent that selectively retains nitrogen and other components until they are released when the pressure is vented to the atmosphere. This cycle is controlled by a motorized valve and protected from over pressurization by the compressor's pressure relief valve.

Oxygen provided by the CARE ZY5BA Oxygen Concentrator is delivered to the user by means of standard oxygen supply tubing and a standard nasal cannula or oxygen mask. A standard bubble humidifier may be used, if physician has prescribed an oxygen humidifier as part of therapy.

The front panel of the CARE ZY5BA contains the controls and indicators. These include the status lights (included power light, normal oxygen light, low oxygen light and service required light), standard power switch, flow meter and the flow meter knob, a circuit breaker which could reset the device after electrical overload shutdown, an oxygen outlet which oxygen is dispersed through, a monitor display which indicates the condition of system status (included pressure status, oxygen purity status and electric hour meter, etc). The user could operate the device conveniently according the instructions.

Technological Characteristics:

Technologies utilized by the CARE ZY5BA Oxygen Concentrator bring forth no new questions of safety and effectiveness. These technologies are also currently being used in the identified predicate device.

Bench performance testing has demonstrated that the CARE ZY5BA Oxygen

Concentrator is substantially equivalent to the predicate device.

Testing:

Laboratory testing was conducted to validate and verify that the CARE ZY5BA Oxygen Concentrator met all design specifications and was substantially equivalent to the predicate device. This testing consisted of all environmental testing identified in the FDA's "Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators (October 1, 1993)". Additional testing was performed to demonstrate compliance with the standards of ASTM F1464 and ISO 8359. Finally, a hazard analysis of the system and its software was performed and testing was conducted to validate the systems overall operation. The CARE ZY5BA Oxygen Concentrator has also been tested to assure compliance to the requirements of various published standards, including IEC60601-1, IEC60601-1-2, IEC60601-1-4, and ISO14971.

Conclusion:

The conclusions drawn from the testing of the CARE ZY5BA Oxygen Concentrator demonstrates that the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Foshan Care Medical Technology Company, Limited
C/O Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-9526

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Re: K102245
Trade/Device Name: CARE ZY5BA Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: October 28, 2010
Received: November 4, 2010

Dear Mr. Mouser:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Pearse

Anthony D. Watson, B.S., M.S., M.B.A.
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

NOV - 9 2010

510(k) Number (if known): K102245

Device Name: **CARE ZY5BA Oxygen Concentrator**

Indications for Use:

The CARE ZY5BA Oxygen Concentrator is intended for use as an oxygen concentrator to provide supplemental low flow oxygen therapy in the home, nursing homes, patient care facilities, etc. The CARE ZY5BA Oxygen Concentrator is available by prescription only under the supervision of a physician, and is not intended to support or sustain life.

Prescription Use __X_____ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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