K083559

SEP – 4 2009

江苏鱼跃医疗设备有限公司
JIANGSU YUYUE MEDICAL SUPPLY & EQUIPMENT CO., LTD
Yun Yang Industrial Park Dan Yang City, Jiangsu, CHINA 212300
Tel: (86)511-86900809 Fax: (86)511-86900800

4.2.3. Common Name: Oxygen concentrator

4.2.4. Calcification Name: Oxygen concentrator, Portable

4.2.5. Regulation Number: 21 CFR 868.5440

4.2.6. Proposed Regulation Class: Class II

4.2.7. Device Product Code: CAW

4.2.8. Medical Specialties: Anesthesiology

4.3. DEVICE DESCRIPTION

The Yuyue OxygenMax™ 7F-5 oxygen concentrator (" the Yuyue 7F-5") is used by patients with respiratory disorders who require supplemental oxygen. The device can be used in the home or an institutional environment. The device is not intended to sustain or support life. The device is used with a nasal cannula to direct oxygen from the device to the patient. The Yuyue 7F-5 provides oxygen in pulsed demand flow dosages at settings of 1 through 5. The oxygen concentration level of the output gas ranges from 90% to 94%. The Yuyue 7F-5 uses a standard AC power of 120 V/60 Hertz.

The Yuyue 7F-5 uses a molecular sieve and pressure swing adsorption methodology to produce the oxygen gas output. Ambient air enters the device, is filtered and then compressed. This compressed air is then directed toward one of two nitrogen adsorbing sieve beds. Concentrated oxygen exits the opposite end of the active sieve bed and is directed into an oxygen reservoir where it is delivered to the patient in specific volumes during the inhalation portion of a detected breath The basic technology of The Yuyue 7F-5 is commonly used and equivalent to other FDA approved oxygen concentrators under the same Product Code of CAW. The principles of operation are equivalent to the predicate device.

4.4. INDICATIONS FOR USE

The YuYue OxygenMax™ 7F-5 Oxygen Concentrator is intended solely for medical use in oxygen therapy programs under the supervision of a physician. It is intended to provide supplemental oxygen to patients with respiratory disorders for use in the home or health care facility. This device is available by prescription only and is not intended to support or sustain

江苏鱼跃医疗设备有限公司
JIANGSU YUYUE MEDICAL SUPPLY & EQUIPMENT CO., LTD
Yun Yang Industrial Park Dan Yang City, Jiangsu, CHINA 212300
Tel: (86)511-86900809 Fax: (86)511-86900800

life.

4.5. PREDICATE DEVICE

4.5.1. Predicate Device Name: John Bunn® O2 Premier oxygen concentrator

4.5.2. Device FDA 510 (k) Number: K844223

4.6. SUBSTENTIAL EQUIVALENCE

The Yuyue 7F-5 (the subjective device) is determined to be substantially equivalent to the predicate device, *John Bunn O2 Premier* oxygen concentrator. Both the predicate device and the subject device are designed and manufactured by Yuyue Medical. Except using different trade name and model name, the subjective device and the predicate device is identical in the intended use, specification and other key characteristics. In addition. The subject device uses 120 V/60Hz AC power only, and the predicate device has two models, using 120V/60Hz and 220V/50 Hz respectively. But the counterpart model of the two devices, Yuyue 7F-5 and John Bunn O2 Premier, JB0160-010/015, uses the identical power supply, 120 V/60 Hz.

4.7. NON-CLINICAL PERFORMANCE

The bench tests of Yuyue 7F-5 conform the following recognized standards:

- ISO 8359:1996: Oxygen concentrators for medical sue – Safety requirements
- ASTM F1464-93 (2005): Standard Specification for Oxygen Concentrators for Domiciliary Use
- IEC 60601-1-2:2001: Medical Electrical Equipment – Sec 1.2 – Collateral standard: Electromagnetic compatibility
- FDA Reviewer Guidance document "Excerpts Related to EMI from November 1993" as appropriate to the area of usage.

The results of the testing have shown that the Yuyue 7F-5 oxygen concentrator is safe and effective for its intended use and substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP - 4 2009

Jiangsu Yuyue Medical Supply & Equipment Company, Limited
C/O Norman F. Estrin, Ph.D.
President
Estrin Consulting Group, Incorporated
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K083559
Trade/Device Name: Yuyue OxygenMax™ 7F-5 Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: August 26, 2009
Received: August 28, 2009

Dear Dr. Estrin:

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,

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: **Yuyue OxygenMax™ 7F-5 oxygen concentrator** __

Indications for Use:

The YuYue OxygenMax™ 7F-5 Oxygen Concentrator is intended solely for medical use in oxygen therapy programs under the supervision of a physician. It is intended to provide supplemental oxygen to patients with respiratory disorders for use in the home or health care facility. This device is available by prescription only and is not intended to support or sustain life.

Prescription Use __Yes_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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

510(k) Number: K083559