Chapter 4. 510(k) Summary K121531

JUL 17 2012

510(k) Summary

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

1. Submitter Information

- Establishment Registration Number: 3004443928
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2. Application Correspondent

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- Contact Person (Title): Ms. Sabrina Wei (Project Manager)
- E-mail: sabrinawei@hotmail.com

3. Subject Device Information:

- Product Code: CAW
- Regulation Number: 868.5440
- Class: 2
- Review Panel: Anesthesiology
- Classification Name: Generator, oxygen, portable
- Trade Name: A&J 5L POCA series Oxygen Concentrator
- Model: POCA01B, POCA03, POCA04, POCA05, POCA06

4. Predicate Device Information:

- 510(k) Number: K071608
- Sponsor: Zhongshan A&J Medical Equipment Co., Ltd.
- Classification Name: Generator, oxygen, portable
- Trade Name: A&J 5L Oxygen concentrator
- Product Code: CAW
- Model: POCA01

5. Device Description

A&J 5L POCA series Oxygen concentrator is AC power electrically operated. 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 your 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 value and protected from over pressurization by the compressor's pressure relief value.

Oxygen provided by the A&J 5L POCA series Oxygen concentrator is delivered to the user by means of standard oxygen supply tubing and a standard nasal cannula or mask. A standard bubble humidifier may be used, if physician has prescribed an oxygen humidifier as part of therapy.

The front panel of the A&J 5L POCA series Oxygen concentrator 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 to the instructions.

6. Intended Use

A&J 5L POCA series Oxygen Concentrator is intended for use as an oxygen concentrator to provide supplemental low flow oxygen therapy at home, in nursing homes, at patient care facilities. A&J 5L POCA series Oxygen concentrator is available by prescription only under the supervision of a physician.

7. Contraindication

The device is not intended to support or sustain life.

8. **Performance Summary**

Technologies utilized by the A&J 5L POCA series Oxygen Concentrator conduces no questions of safety and effectiveness. The same technologies are being used on the identified predicate device. Bench performance testing has demonstrated that the A&J 5L POCA series Oxygen Concentrator is substantially equivalent to the predicate device.

9. **Testing**

Laboratory testing was conducted to validate and verify that the A&J 5L POCA series Oxygen Concentrator met all design specifications and was substantially equivalent to the predicate device. The testing consisted of all environmental testing identified in the FDA's "Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators (October 1, 1993)". Testing was also performed to demonstrate the sponsored device series achieves the standards' requirements of ASTM F1464 and ISO 8359.

Hazard analysis of the system and its software was performed and testing was conducted to validate overall operation of the system. The A&J 5L POCA series Oxygen Concentrator has also been tested to assure its compliance to the requirements of various standards of IEC60601-1, IEC60601-1-2.

10. **Comparison to Predicate Device**

Compare the subject devices to the predicate device: they are same in design principle, intended use, functions, performance, material and applicable standards. The main difference between subject devices and the predicate device is enclosure style and the following list notes. These differences do not raise any new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Judgment
Device Name	A&J 5L POCA series Oxygen Concentrator, Models: POCA01B, POCA03, POCA04, POCA05, POCA06	A&J 5L Oxygen Concentrator, Model: POCA01	--
Operation and Storage Environment			
Operating Conditions	Temperature: 10~40 ℃ Humidity: 30~70 % Atmospheric Pressure: 50~106 kPa (7.3~15.4 psi)	Temperature: 10~35 ℃ Humidity: 30~70 % Atmospheric Pressure: 50~106 kPa (7.3~15.4 psi)	SE Note 1

Elements of Comparison	Subject Device	Predicate Device	Judgment
Storage Conditions	Temperature: -40~70 ℃ Humidity: 10~100 % Atmospheric Pressure: 50~106 kPa (7.3~15.4 psi)	Temperature: -40~70 ℃ Humidity: 10~100 % Atmospheric Pressure: 50~106 kPa (7.3~15.4 psi)	SE
Safety Factor			
Power Input	115V, 60Hz, 3.1A	115 V, 60 Hz, 1.8A (Max.)	SE Note 2
Degree of Protection Against Electric Shock	Type B Equipment	Type B Equipment	SE
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	SE
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	SE
Performance and Specification			
Delivery Rate	0 to 5 LPM	0 to 5 LPM	SE
Oxygen Percentage	93% ± 2%	93% ± 2%	SE
Outlet Pressure	8.5 psi (58.6 kPa)	8.5 psi (58.6 kPa)	SE
Sound Level	< 45 dbA (Overall Average)	45-47 dbA (Overall Average)	SE Note 3
Operating System	Time Cycle / Pressure Swing Adsorption	Time Cycle / Pressure Swing Adsorption	SE
Mode of Operation	Continuous	Continuous	SE
Others			
Biocompatibility	All the patient contacting material and gas pathway material are the same with predicate device.	Conduct the following output gases tests to replace the biocompatibility testing for the materials in the gas pathway: - Particulate Matter per EPA PM 2.5; - Volatile Organic Compounds per ASTM D5466 or equivalent; - Measurement of output gas for carbon monoxide; - Measurement of output gas for carbon dioxide; - Measurement of output gas for ozone.	SE

Elements of Comparison	Subject Device	Predicate Device	Judgment
Accessories	All the specified accessories are the same with predicate device.	All the following accessories are not included in the package, and need to use the legitimate marketing products in the United States: - Oxygen Mark - Nasal Cannula - Bubble Humidifier - Oxygen Outlet Connector - Oxygen Tubing	SE

Note:

1) The operating temperature range of subject device is wider than predicate device. This can seem to be SE.
2) Although the power input of subject device is different from predicate device, both of them are complied with IEC 60601-1, the difference will not affect the SE.
3) The sound level of subject device is lower than predicate device, and both results are complied with ISO 8359. The difference will not affect the SE.

11. Conclusion

As a summary to the above testing results and performance specifications, A&J 5L POCA series Oxygen Concentrator is as same safe and effective as the predicate device, therefore, is Substantial Equivalent to the predicate device.

12. Summary Prepared Date: 2012-06-19

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

Zhongshan A&J Medical Equipment Company, Limited
C/O Mr. Ned Devine
Responsible Third Party Official
Underwrites Laboratories, Incorporated
333 Pfingsten Road
Northbrook, Illinois 60062

JUL 17 2012

Re: K121531
Trade/Device Name: A&J 5L POCA series Oxygen Concentrator, models: POCA01B, POCA03, POCA04, POCA05 & POCA06
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: June 26, 2012
Received: July 2, 2012

Dear Mr. Devine:

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,

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

Chapter 3. Indications for Use

Indications for Use

510(k) Number (if known):

Device Name: A&J 5L POCA series Oxygen Concentrator, models: POCA01B, POCA03, POCA04, POCA05, POCA06

Indications for Use:

A&J 5L POCA series Oxygen Concentrator is intended for use as an oxygen concentrator to provide supplemental low flow oxygen therapy at home, in nursing homes, at patient care facilities. A&J 5L POCA series is available by prescription only under the supervision of a physician.

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

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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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