CHAPTER 1. 510(K) SUMMARY

This 510(k) summary of safety and effectiveness for Jumao Oxygen Concentrator is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Table 5-1 General Information

<table>
<thead>
<tr>
<th>Applicant:</th>
<th>Danyang Jumao Healthcare Equipment Co., Ltd.</th>
</tr>
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<tbody>
<tr>
<td>Address:</td>
<td>No.89 Shuangfeng Road, Jiepai town, Danyang, Jiangsu, P.R.China</td>
</tr>
<tr>
<td>Contact Person:</td>
<td>Qing Wang</td>
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<tr>
<td>Telephone:</td>
<td>(86 511)- 86379811</td>
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<tr>
<td>Fax:</td>
<td>(86-511)-86379811</td>
</tr>
<tr>
<td>Email:</td>
<td><a href="mailto:kenwqing@gmail.com">kenwqing@gmail.com</a></td>
</tr>
<tr>
<td>Date of Preparation</td>
<td>August 10, 2008</td>
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<tr>
<td>Device Name:</td>
<td>JUMAO OXYGEN CONCENTRATOR</td>
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<tr>
<td>Model No.</td>
<td>JM-07000Hi, JM-07000i, JM-07000</td>
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<tr>
<td>Classification Name</td>
<td>Portable Oxygen Concentrator</td>
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<tr>
<td>Classification Number</td>
<td>868.5440</td>
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<td>Device Class:</td>
<td>Class II</td>
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<td>Product Code:</td>
<td>CAW</td>
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<td>Classification Panel</td>
<td>Anesthesiology</td>
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<tr>
<td>Type of submission</td>
<td>Traditional 510K</td>
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</table>

Intended use:

The intended function and use of the Jumao Oxygen Concentrator 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.

Indications for Use:

The intended function and use of the Jumao Oxygen Concentrator 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.

Device Description
The Jumao Oxygen Concentrator is a Pressure Swing Adsorption (PSA) type oxygen concentrator. The output of oxygen is 0.5 to 5 liter per minute. Room air enters the piston type compressor via a series of filters for removing dust particles. The output compressed air is directed by a pneumatic valve into one of the two sieve beds which is full of adsorption material - molecular sieve. Nitrogen is adsorbed by the molecular sieve as the pressure increases; oxygen flows through the molecular sieve and concentrates at the sieve bed bottom. The enriched oxygen is divided into two streams; one stream enters a storage tank. The pressurized oxygen is regulated down to the suitable pressure, an adjustable flow meter and out to the patient. At the same time the second bed is in exhausted status, the molecular sieve desorbs nitrogen as the pressure decreases; another oxygen stream from first bed enters the bottom of the second bed, promotes purging the nitrogen and is exhausted into the atmosphere. Two sieve beds exchange the role of oxygen concentration and continue to produce 90% oxygen to the patient.

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 with the JM-07000i/ JM-07000 models, if desired.

The JM-07000Hi model incorporates the Humidiflow humidifier to provide humidified oxygen to the user. The Humidiflow attaches to the inlet of the air compressor and to the outlet oxygen used in oxygen concentrators and operates as a mass exchanger to transfer the room air humidity to the patient gas. The Humidiflow humidifier has been cleared by FDA (K062091).

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.

The basic technology of the JuMao oxygen concentrator is equivalent to the other approved oxygen concentrator. The principles of operation are equivalent to the noted predicate device, Invacare Platinum 5 Oxygen Concentrator by Invacare Corporation, 510(k) K020386.

Predicate Devices:
- Invacare Platinum 5 Oxygen Concentrator by Invacare Corporation, 510(k) K020386.
- LONGFEI LFY-I-5 OXYGEN CONCENTRATOR by Zhejiang longfei industrial co., ltd, K033405
- Drive solstice oxygen concentrator, by Medical depot, K080391
- A&J poce01 oxygen concentrator, by Zhongshan A&J medical equipment co., ltd, K071608

Substantial Equivalence Information:
<table>
<thead>
<tr>
<th>Substantial Equivalence Comparison Table</th>
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<tr>
<td><strong>DanYang JuMao Healthcare Equipment CO., Ltd</strong></td>
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<tr>
<td><strong>Product name</strong></td>
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<td><strong>Model No</strong></td>
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<td><strong>510(K) Number</strong></td>
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<td><strong>Concentration levels</strong></td>
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<td><strong>Delivery rate</strong></td>
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<td><strong>Outlet pressure</strong></td>
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<td><strong>Thermal protection on compressor</strong></td>
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<tr>
<td><strong>Low oxygen purity</strong></td>
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<td><strong>compressor 40 psi pressure relief valve</strong></td>
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<tr>
<td><strong>Electrical rating</strong></td>
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<td><strong>Power consumption</strong></td>
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<td><strong>Filters</strong></td>
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<tr>
<td><strong>dimensions</strong></td>
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<td><strong>Weight (lbs)</strong></td>
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<td><strong>Sound level</strong></td>
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<td><strong>Compressor</strong></td>
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<td><strong>Humidifier</strong></td>
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Table 5-1 Substantial Equivalence Comparison Table

As the chart above show, **Jumao Oxygen Concentrator** is comparable to its predicate. All devices have the same intended use for the same patient population, extract oxygen from air using the same methodology, provide comparable oxygen purity and are powered in the same manner. There are some small differences in the size, sound level, and compressor pressure between the **Jumao Oxygen Concentrator** and the predicate device, which do not affect the safety and effectiveness of the device.

**Safety and Performance Data:**
Safety and Performance Testing: The **Jumao Oxygen Concentrator** has been tested in accordance with the following standards:

- ISO 8359:1996 Oxygen Concentrator for Medical Use-Safety Requirements
- IEC60601-1, 2005 Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
- UL 1431, 2nd ED., 1996 UL Standard for Safety for personal Hygiene and Health Care Appliances Equipment

The safety and performance data found in this submission shows that the **Jumao Oxygen Concentrator** performs as intended and in a manner that is substantially equivalent to the predicate device.
All the components/materials/process used in the Jumao Oxygen Concentrator's gas path and patient contacting portion are identical to those of the Predicate Devices, see Table S2-1. Therefore, the Jumao Oxygen Concentrator meets biocompatibility standards in accordance with FDA Guidance Document FDA's Blue Book Memorandum #G95-1, “Use of international Standard ISO-10993, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing” (G95-1).

Conclusion:
The data submitted in this 510(K) Premarket Notification supports the finding that this device is substantially equivalent with respect to the intended use, technology, functionality, and safety features to the legally marketed Predicate Device. Therefore, we believe that this device meets the requirement for a “Substantial Equivalence” decision in accordance with the 510(K) guidelines.
Danyang Jumao Healthcare Equipment Company, Limited  
C/O Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25th Street NW  
Buffalo, Minnesota 55313

Re: K090007  
Trade/Device Name: Jumao Oxygen Concentrator  
Regulation Number: 21 CFR 868.5440  
Regulation Name: Oximeter  
Regulatory Class: II  
Product Code: CAW  
Dated: July 7, 2009  
Received: July 8, 2009

Dear Mr. Job:

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 Director
Division of Anesthesiology, General Hospital, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
CHAPTER 4.  INDICATIONS FOR USE

510(k) Number (if known): K090007

Device Name: Jumao Oxygen Concentrator

Indications for Use:

The intended function and use of the Jumao Oxygen Concentrator 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.

Prescription Use  X  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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

\[Signature\]

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

510(k) Number: K090007