November 9, 2023

Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
℅ Jinghua Zhou
Regulation Control Manager
Guangzhou Junyi Information Technology Co., Ltd.
Room 215, Huaming Building, Chebei Road
Guangzhou, Guangdong 511660
China

Re: K230969
Trade/Device Name: Oxygen Generator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: October 10, 2023
Received: October 10, 2023

Dear Jinghua Zhou:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230969

Device Name
Oxygen Concentrator

Indications for Use *(Describe)*
The JUMAO Oxygen Concentrator is intended 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 - 510(k) Summary

K Number: K230969
Date of Summary Preparation: March 31, 2023
Date of Summary modification: September 28, 2023

1. Submitter's Identifications

Submitter's Name: Jiangsu Jumao X-Care Medical Equipment Co., Ltd.
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2. Correspondent’s Identifications

Correspondent’s Name: Guangzhou Junyi Information Technology Co., Ltd.
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3. Name of the Device

Device Classification Name: Oxygen concentrator, Portable
Product Name: Portable oxygen generator
Trade Name: Oxygen Concentrator
Model: JMC5A Ni
Classification Panel: Anesthesiology
Product Code: CAW
Regulation Number: 21 CFR 868.5440
Device Classification: Class II

4. The Predicate Devices

Predicate device: K090007 Oxygen Concentrator

5. Device Description

JMC5A Ni oxygen concentrator is made up of mainframe and flowmeter. It is an electronically operated device that separates oxygen from ambient air. It provides

high concentration of oxygen directly to patient/user through a nasal cannula or other methods.

The Jumao Oxygen Concentrator is a Pressure Swing Adsorption (PSA) type oxygen concentrator which takes 120V ~ power source as power source. 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 93% oxygen to the patient.

6. Intended Use of Device

The JUMAO Oxygen Concentrator is intended 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.

7. Summary of Substantial Equivalence

Table 1

	Proposed device	Predicate device	Comparison
510k Number	------	K090007	------
Product Code	CAW	CAW	Same
Proprietary Name	Oxygen Concentrator	Oxygen Concentrator	------
Model	JMC5A Ni	JM-07000Hi, JM-07000i, JM-07000	------
Manufacturer	Jiangsu Jumao X-Care Medical Equipment Co., Ltd.	Jiangsu Jumao X-Care Medical Equipment Co., Ltd.	------
Indications for use	The JUMAO Oxygen Concentrator is intended to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen	The intended function and use of the Jumao Oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders,	Same

	from room air, by way of a molecular sieve. It is not intended to sustain or support life.	by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.	
Intended patient population	The device is intended for use in adults.	The device is intended for use in adults.	Same
Structure and main components	JMC5A Ni oxygen concentrator is made up of mainframe and flowmeter. 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 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.	Same Same as JM-07000i and JM-07000 models.
Filters	Cabinet, out HEPA, Compressor inlet	Cabinet, out HEPA, Compressor inlet	Same
HEPA Filter	Same as predicate device	Same as proposed device	Same
Oxygen sensor	Model: OXY-III-B, Gasboard-7500K	DigiFLO Concentrator ANALYZER (clear by FDA, K072469)	Different The oxygen sensor used in proposed device does not have a K number, while the sensor used in predicate device has a K number. The oxygen sensor of predicate device has been tested with equipment. The difference does not affect the effectiveness

			and safety of the proposed device.
Compressor	Model: 1120-2-1-3, 1121-1-2-1(1000460)	GSE-ZW400D2-90 Compressor, Thomas based double wobble	Different Proposed device and predicate device use compressors from different manufacturers. The compressor of predicate device has been tested with equipment. The difference does not affect the effectiveness and safety of the proposed device.
Material of main components	Components and associated materials which contact the gas pathway to the patient: filter-High efficiency particulate air (HEPA) filter paper; Compressor- ASM; Heat exchanger-Aluminum; Valve assembly-Aluminum; Molecular sieve module-Li2O·Al2O3·(2.2±0.2) SiO2·9/2H2O; Silicone tube-Silicone; Product tank-ABS; Bacilli filter- Non-woven polyester fiber; Flow meter-Acrylic; Check valve-Fluororubber; Oxygen outlet connector-Copper; Commute valve-Fluororubber; Muffler, Enclosure, Base-ABS; Transformer, AC fan,	Components and associated materials which contact the gas pathway to the patient: filter-High efficiency particulate air (HEPA) filter paper; Compressor- ASM; Heat exchanger-Aluminum; Valve assembly-Aluminum; Molecular sieve module-Li2O·Al2O3·(2.2±0.2) SiO2·9/2H2O; Silicone tube-Silicone; Product tank-ABS; Bacilli filter- Non-woven polyester fiber; Flow meter-Acrylic; Check valve-Fluororubber; Oxygen outlet connector-Copper; Humidifier bottle-(Cup body-translucent PE, Cup lid-black ABS,	Same

	Wheel, Control panel, Power cord-ASM; PCB- Flame Retardant Copper Clad Epoxy E Glass Cloth Laminate	Filter tube-transparent PVC); Nasal oxygen cannula-PVC; Commute valve-Fluororubber; Muffler, Enclosure, Base-ABS; Transformer, AC fan, Wheel, Control panel, Power cord-ASM; PCB- Flame Retardant Copper Clad Epoxy E Glass Cloth Laminate	
Power supply	AC120V, 60Hz; Current: 3.5A; Power: 450VA	AC115V, 60 Hz, 4.3 A; Power consumption: 4.3 amps average @ 5L/min (400W)	Different Input voltage, rated current and rated input power of proposed device are different from those of predicate device. Proposed device is complied with safe standards. These difference do not affect the safety and effectiveness of proposed device.
Oxygen concentration	93% ± 3% at 0.5 to 5L/min (after turning on 5 minutes)	95.6% to 87% at all flow rates	Similar 1. The expression of the proposed device is more standardized, and the requirements for oxygen concentration under the conditions of 0.5 to 5L/min are specified. 2. The oxygen concentration range of the proposed device is narrower than that of the predicate device. Oxygen concentration of proposed device can reach 93%±3% within the oxygen flow range,

			which is superior to the predicate device. Proposed device is complied with ISO80601-2-69. The difference does not affect the effectiveness and safety of the proposed device.
Oxygen flow	0.5～5L/min	0.5 – 5 LPM	Same
Outlet pressure	38kPa±5kPa	38kPa±5kPa	Same
Noise	Sound level: ≤ 50.5dB (A); Acoustic power level: 58.5dB (A)	52 dB(A)	Different Sound level of proposed device is lower than that of predicate device. Acoustic power level is added to the propsed device. Proposed device is complied with ANSI AAMI ES60601-1. The difference does not affect the effectiveness and safety of the proposed device.
Release pressure by machine operation	250kPa±50kPa	40bsi (275kPa)	Different Range of release pressure of proposed device is larger than that of predicate device. Proposed device is complied with safe standards. The difference does not affect the effectiveness and safety of the proposed device.
Net weight	16.1kg	52 pounds (23.6kg)	Different Net weight of proposed device is

			lighter than that of predicate device. Proposed device is complied with ANSI AAMI ES60601-1. The difference does not affect the effectiveness and safety of the proposed device.
Dimension	330×260×540(mm)	28” (710mm)H x 17”(432) W x 15” (381)D	Different Dimension of proposed device is smaller than that of predicate device. Proposed device is complied with ANSI AAMI ES60601-1. The difference does not affect the effectiveness and safety of the proposed device.
Electric Classification	Class II, Type BF	Class II, Type B	Similar They are both Class II. But safety type of applied part is different, proposed device is type BF, predicate device is type B. Proposed device is complied with ANSI AAMI ES60601-1. The difference does not affect the effectiveness and safety of the proposed device.
Alarm	Start-up fail alarm	Oxygen monitor, low-flow	Same Different expressions, in fact the same principle.

	Low oxygen concentration alarm	Low oxygen purity (JM-07000Hi, JM-07000i)	Same Different expressions, in fact the same principle.
	Power supply failure alarm	Power failure	Same Different expressions, in fact the same principle.
	Pressure failure alarm 1.Outlet block, oxygen flowrate below 0.6 Lpm; 2.Compressor stop	Compressor 40 psi pressure relief valve Thermal protection on compressor	Different Proposed device design takes into account compressor stop, outlet block, oxygen flowrate below resulting in pressure failure alarm. The alarm function is complied with IEC 60601-1-8. The difference does not affect the effectiveness and safety of the proposed device.
Mode of operation	Continuous duty	Continuous duty	Same
Normal operating ambient	Temperature range: 5℃～40℃ (41℉～104℉) Relative humidity: ≤80% Atmospheric pressure: 86kPa ～ 106kPa (12.47psi～15.37psi) 1828 meter (5997 feet) height above sea level	10 ºC – 35 ºC 30-75% Relative Humidity (non-condensing) Up to 7,500 feet above sea level	Different The range of operating temperature range and relative humidity of proposed device is wider than those of predicate device. The height above sea level of proposed device is less than that of predicate device.
Storage and transport ambient	Temperature Range: 0℃～+55℃ (32℉～+131℉) Relative Humidity Range: 10%～90% Atmospheric pressure: 70kPa ～ 106kPa (10.2psi～15.37psi)	-40 ºC to 70 ºC, 10% to 100% R.H.	Different The temperature range and relative humidity range of proposed device are both narrow than those of predicate device. Atmospheric pressure is added to

			proposed device. The range of storage and transport of proposed device is narrower than that of predicate device. The difference does not affect the effectiveness and safety of the proposed device.
Software control	Yes	Yes	Same
Patient interface type	Visual, direct contact type patient interface	Visual, direct contact type patient interface	Same
Standard	IEC 60601-1-2:2014+ A1:2020 IEC TR 60601-4-2:2016 AIM Standard 7351731:2021 ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 IEC60601-1-11:2015 IEC60601-1-8:2012 ISO80601-2-69:2014 ISO18562-1:2017 ISO18562-2:2017 ISO18562-3:2017 ISO10993-1:2018 ISO10993-5:2009 ISO10993-10:2021 ISO10993-23:2021	ASTM 1464-93 (2005) ISO 8359:1996 IEC 60601-1:2005 IEC 60601-1-2:2007 UL 1431, 2nd ED., 1996	Similar 1. In the test standards for proposed device and predicate device: basic safety and performance requirements for medical electrical equipment (ES/IEC60601-1), and electromagnetic compatibility (IEC60601-1-2), the two standards have the same number, but different age numbers; 2. Standard IEC60601-1-11 and standard UL 1431 are similar. The requirements of ISO80601-2-69 supersede ASTM 1464 and ISO 8359. 3. Proposed device adds IEC TR 60601-4-2, AIM Standard 7351731, ISO18562-1,

			ISO18562-2, and ISO18562-3 test. 4. Proposed device adds ISO 10993-5, ISO 10993-10, ISO 10993-23 test. Proposed device are tested against current applicable standards, and the test results meet the standard requirements. These difference do not affect the effectiveness and safety of the proposed device.
Discussion for Substantially Equivalent (SE)	The proposed device JMC5A Ni oxygen concentrator has the same indications for use, intended patient population, structure and main components, filters, HEPA filter, material of main components, oxygen flow, outlet pressure, alarm (start-up fail alarm, low oxygen concentration alarm, power supply failure alarm), mode of operation. The main differences are oxygen sensor and compressor used, power supply, oxygen concentration, noise, release pressure by machine operation, net weight, dimension, application types of electrical safety, pressure failure alarm, normal operating ambient, storage and transport ambient, test standards. These differences are slight and do not affect the effectiveness and safety of the device, through the above comparative analysis. The proposed device JMC5A Ni oxygen concentrator is determined to be Substantially Equivalent (SE) to the predicate device, JM-07000Hi, JM-07000i, JM-07000 oxygen concentrator in respect of safety and effectiveness.		

Note: The oxygen concentrator can be used with accessories (i.e, nasal cannula, humidifier bottle) available in the market.

8. Non-Clinical Tests Submitted:

The following non-clinical testing was provided in this 510(k) submission:

Biocompatibility Testing

- According to ISO 10993-1:2018 and ISO 18562-1:2017, we performed the biocompatibility evaluation and test of the dry breathing gas pathway:

1. Performed toxicological evaluation according to ISO 18562-1:2017. Performed evaluation of emissions of ozone, carbon monoxide, carbon dioxide per recommendations in ISO 18562-1:2017.
2. Performed test for emissions of particulate matter according to ISO 18562-2:2017.

3. Performed test for emissions of volatile organic compounds according to ISO 18562-3:2017.
- According to ISO 10993-1:2018, we performed biocompatibility test for the parts that may directly contact the intact skin of the patient or operator, including in vitro cytotoxicity test per ISO 10993-5:2009, skin sensitization test per ISO 10993-10:2021, irritation test per ISO 10993-23:2021.

Electrical Safety and Electromagnetic Compatibility Testing

- The Device was tested and complied with the applicable requirements of the following standards: ANSI AAMI ES60601-1, IEC 60601-1-2, IEC TR 60601-4-2, AIM Standard 7351731, IEC 60601-1-11, IEC 60601-1-8, ISO 80601-2-69, demonstrated that the basic safety and performance of the device met the requirements.

Software Verification and Validation

- Software verification and validation was performed, and it was demonstrated that the software performs as intended according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

9. Concise summary for performance testing

From the performance testing - bench, we have a brief summary as follow:
1. Performance Test (Appearance requirement, Gas tightness, Sound pressure level, Operation, Accuracy of continuous flowrate, Oxygen yield and oxygen concentration, Oxygen output pressure, Alarm, Error of flowmeter, Leakage current, Dielectric strength).
2. Use Life Test (Accelerated life test, and performance test after accelerated life test).
3. Cleaning and Disinfection Verification (simulated cleaning and disinfection test, and performance test after simulated cleaning and disinfection test).
All the bench test results are provided in Performance Test Report.

10. Usability Study

The JMC5A Ni oxygen concentrator was performed usability study separately by similar methods.
Testing of 15 participants was conducted showing that the participants were able to understand the user manual and labeling and were able to safely and effectively use the device.

11. Clinical Study

No clinical testing has been performed.

12. Conclusions

After analyzing both bench and external laboratory testing data, the intended use and supporting data can conclude that the device in the submission is substantially equivalent to the predicate device.