July 20, 2023

Zhengzhou Olive Electronic Technology Co., Ltd.
℅ Boyle Wang
General Manager
Shanghai Truthful Information Technology Co., Ltd.
RM. 1801, No. 161, East Lujiazui Rd., Pudong
Shanghai, Shanghai 200120
China

Re: K222920
Trade/Device Name: Oxygen concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: June 16, 2023
Received: June 16, 2023

Dear Boyle Wang:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

James J. Lee -S

James J. Lee, Ph.D.
Director, Division of Sleep Disordered Breathing,
Respiratory and Anesthesia
Office of Health Technologies 1, Ophthalmic, Anesthesia,
Respiratory, ENT & Dental Devices
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)*
K222920

Device Name
Oxygen concentrator

Indications for Use *(Describe)*
The Oxygen concentrator provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve, it can be used in the home or health care facility. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) number: K222920
This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

1.0 Submitter's information

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Date of Preparation: Sep.22, 2022

Prior submissions

This is the first submission, there is no prior submission.

Designated Submission Correspondent

Mr. Boyle Wang
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2.0 Device information

Trade name: Oxygen concentrator
Common name: Oxygen concentrator
Regulation name: Oxygen concentrator, Portable
Model(s): OLV-5S, OLV-10S.

3.0 Classification

Production code: CAW
Regulation number: 21 CFR 868.5440
Classification: Class II
Panel: Anesthesiology

4.0 Predicate device information

Manufacturer: AirSep Corporation

Device: Deployable Oxygen Generator System - Small (DOGS-S)
510(k) number: K150930

5.0 Indication for Use Statement

The Oxygen concentrator provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve, it can be used in the home or health care facility. It is not intended to sustain or support life.

6.0 Device description

The oxygen concentrator adopts pressure swing adsorption principle, which can separate oxygen, nitrogen and other gas from the air, at constant temperature. As soon as power is connected, the air is taken in and compressed by oilless air compressor through filtering, then the compressed air goes through the cooler and it is cooled. After that, the air is taken into absorption tower by control valve and the oxygen can be separated in the absorption tower. At the same time, the high purity oxygen is collected into the oxygen tank, and it goes through the flow meter and humidifier, finally the oxygen that meets medical standards can be supplied. Oxygen is generated by pure physical method.
The maximum altitude the subject device can operate without degradation of concentration is 2000m.

7.0 Non-Clinical Test Conclusion

The device has been tested and verified in various phases, internal testing, verification and validation as well as external testing and validation. The design was verified throughout the design process. Risk analysis was done, appropriate measures were implemented and their effectiveness verified. External test house was used to confirm compliance to EMC requirements and standards for electrical safety.

The testing confirms the Oxygen concentrator (OLV-5S, OLV-10S) meets the ISO 80601-2-69 standards for Oxygen Concentrator devices. Testing demonstrates that the product is in compliance to:
IEC 60601-1 Medical electrical equipment-Part 1: General requirements for basic safety, and essential performance.
IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests

The oxygen flow rate and purity at the operating pressure was tested and verified in the Performance Bench Testing section of this submission, the instruction manual and in accordance with:

ISO 80601-2-69	Medical Electrical Equipment, Part 2-69
IEC 60601-1	Safety Requirements (Medical Electrical Equipment Part 1: General Requirements)

IEC 60601-1-2	EMC (Electro Magnetic Compatibility Testing)
IEC 62304	Medical Device Software-Software Life-Cycle Processes, Class B. Moderate Level of Concern, as per FDA software guidance
ISO 10993-1	Biological Evaluation of Medical Devices - Cytotoxicity - Sensitization - Irritation
ISO 18562-1	Biological Evaluation of Breathing Gas pathway -Emission of particle matter -Volatile organic compounds (VOCs)
Compliance with	USP 93% +/-3%

The test platform ensures compliance to recognized consensus standards and therefore does not raise new questions of safety and effectiveness.

8.0 Clinical Test Conclusion

No clinical study implemented for the oxygen concentrator.

9.0 Technological Characteristic Comparison Table

Table 3- General Comparison

Item	Proposed device	Predicated device	Remark
Product Code	CAW	CAW	Same
Regulation No.	21 CFR 868.5440	21 CFR 868.5440	Same
Class	II	II	Same
Product name	Oxygen concentrator	Deployable Oxygen Generator System - Small (DOGS-S)	-
Common Name	Oxygen concentrator	Oxygen concentrator	Same
Classification Name	Oxygen concentrator, Portable	Oxygen concentrator, Portable	Same
510(k) No.	-	K150930	-
Models	OLV-5S, OLV-10S	-	-
Intended Use	The Oxygen concentrator provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve, it can be used in the home or health care facility. It is not intended to sustain or support life.	The Deployable Oxygen Generator System – Small (DOGS-S) is intended for the administration of supplemental oxygen. This device is not intended for life support nor does it provide any patient monitoring capabilities. The system will be operated by trained personnel	Same
Work principle	Pressure swing adsorption	Pressure swing adsorption	Same

	principle, filtering by molecular sieve	principle, filtering by molecular sieve	
Working mode	Continuous	Continuous	Same

Table 4- Performance Comparison

Item	Proposed Device		Predicate Device	Remark
Models	OLV-5S	OLV-10S	Jay-5	-
Power supply	AC 120V±11V, 60Hz±1Hz		AC 100V/240, 50/60Hz	* Gap 1
Max.Input power	500VA	800VA	550W	* Gap 2
Oxygen concentration	93% ± 3%		93% ± 3%	Same
Oxygen flow	0-5L/min	0- 10L/min	0.5~15L/min	* Gap 3
Outlet pressure	20kPa-60kPa		10psig (68kpa)	* Gap 4
Noise	≤70dB (A) under max. flowrate		≤70dB (A)	Same
Electrical classification	Class II Type B		Class II Type B	Same
Alarm	Low Oxygen purity; Low & high pressure; Overheating; Compressor failure; Obstruction of gas pathway; Pressure failure;		Low Oxygen purity O2 Flow High or Low Low power indicator (Battery) Unit malfunction	* Gap 5
Oxygen concentration warning	<82%±3%, indicator light shows dual color (red and green mixed color); <65%±3%, indicator light is shown in red, and and "low concentration" is displayed on the display screen		<85%	* Gap 6
Operating system	Time cycle/ Pressure swing adsorption		Time cycle/ Pressure swing adsorption	Same
Software/Hardware	Analog and digital electronics with microprocessor		Analog and digital electronics with microprocessor	Same
LCD display	Accumulating timing; present timing; timing		Accumulating timing; present timing; timing	Same
Accessories	power supply, power cord, manual		battery pack / lithium ion, power supply, power cord, handle, and manuals	* Gap 7
Dimension	350mmx250mmx670mm		Diameter:10”, height: 33”	* Gap 8

* Gap analysis:

Gap 1, The input power supply is different, input power of the proposed device is more in line with USA network power supply, the difference doe not bring additional use risk;

Gap 2, The input power is different, considering other main parameters are same or

close, the power difference does not bring difference in these main parameters which is critical for using, the difference does not bring additional use risks;
Gap 3, The oxygen flow of the proposed device is in the range of predicate device, the difference does not bring additional use risks;
Gap 4, The outlet pressure of the proposed device is very close to the predicate device, the difference does not bring additional use risks;
Gap 5, The proposed device have more alarm function than the predicate device, the difference does not bring additional use risks;
Gap 6, The proposed device has more detailed oxygen concentration warning level than the predicate device, the difference does not bring additional use risks;
Gap 7, The accessories are not complete same, but they are part of product, the difference does not bring additional use risks;
Gap 8, The two devices' dimension is different, which does not bring additional use risks;

Table 5- Safety Comparison

Item	Proposed Device	Predicate Device	Remark
Sieve Bed	Synthetic Zeolite	Synthetic Zeolite	Same
Gas pathway	Silicone	MATERIAL: G/10 F/R FIBERGLASS TUBE.	* Gap 9
Biocompatibility of materials contacting user	Cytotoxicity, Comply with ISO 10993-5; Irritation, Sensitization, comply with ISO 10993-10, ISO 18562-2:2017, ISO 18562-3:2017.	Cytotoxicity, Comply with ISO 10993-5; Irritation, Sensitization, comply with ISO 10993-10; Particulate Matter Testing Volatile Organic Compound Testing	* Gap 10
Electric safety	Comply with IEC 60601-1:2005+A1:2012, ISO 80601-2-69:2014, IEC 60601-1-8:2006+A1:2012, IEC 60601-1-11:2015	Comply with IEC 60601-1, ISO 80601-2-69	* Gap 11
EMC	Comply with IEC 60601-1-2:2014+A1:2020	Comply with IEC 60601-1-2	Same

* Gap analysis:
Gap 9, The gas pathway material is different, material of the proposed device is closer to state of the art, the difference does not bring additional risk;

Gap 10, The applied biocompatibility of proposed device is closer to state of the art, the difference does not bring additional risk;
Gap 11, The electric safety standards proposed device is closer to state of the art, the difference does not bring additional risk.

10.0 Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the oxygen concentrator is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K150930.