April 28, 2023

Jiangsu Yuyue Medical Equipment & Supply Co., Ltd.
℅ Randy Jiang
Sr. consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K213825
Trade/Device Name: Oxygen Concentrator model 8F-3A, Oxygen Concentrator model 8F-5A
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: March 27, 2023
Received: March 28, 2023

Dear Randy Jiang:

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,

Ting Song -S

For
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)*
K213825

Device Name
Oxygen Concentrator models 8F-3A&8F-5A

Indications for Use *(Describe)*
This oxygen concentrator is intended for using as an oxygen supplement device in the professional healthcare facility and home healthcare environment. It provides high concentration of oxygen to persons requiring oxygen therapy. This device is to be used as an oxygen supplement and is NOT considered life-supporting or life-sustaining.

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

K213825

1. Submission Sponsor

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2. Submission Correspondent

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Office Phone:(512) 327-9997
Contact: Randy Jiang
Title: Senior Technical Consultant

3. Date Prepared

April 24, 2023

4. Device Identification

Trade/Proprietary Name:	Oxygen Concentrator models 8F-3A/8F-5A
Common/Usual Name:	Portable oxygen generator
Classification Name:	Portable oxygen generator
Regulation Number:	21 CFR 868.5440
Product Code:	CAW
Class:	II
Classification Panel:	Anesthesiology

5. Legally Marketed Predicate Device

Predicate Device:

Trade/Proprietary Name:	L4 Oxygen Concentrator (EverFlo)
Common/Usual Name:	Portable oxygen generator

Classification Name:	Portable oxygen generator
Regulation Number:	21 CFR 868.5440
Product Code:	CAW
Class:	II
Classification Panel:	Anesthesiology
510(k) Number:	K061261
Manufacturer:	RESPIRONICS, INC.

6. Indication for Use Statement

This oxygen concentrator is intended for using as an oxygen supplement device in the professional healthcare facility and home healthcare environment. It provides high concentration of oxygen to persons requiring oxygen therapy. This device is to be used as an oxygen supplement and is NOT considered life-supporting or life-sustaining.

7. Device Description

The Yuyue Oxygen Concentrator models 8F-3A/8F-5A is a portable concentrator which could utilize a molecular sieve and pressure swing adsorption to produce the oxygen. The device could separate nitrogen by absorbing through the molecular sieve when the room air enters the device, and allows the enriched oxygen to be collected. The subject device is intended use for adult population.

The subject device contains primary electrical components including main unit, compressor, fan, flowmeter and circuit breaker, the software is moderate level according to FDA software guideline.

The patient contacting components are listed in following table, the biocompatibility test and gas pathway biocompatibility test was conducted to subject device against ISO 10993-5, ISO 10993-10, ISO 18562-1, ISO 18562-2, ISO 18562-3.

Name of Component	Type and Duration of Contact	Direct or Indirect Contact
Compressor	External communicating Device, Long term, > 30 days	Indirect (gas pathway)
Combination valve	External communicating Device, Long term, > 30 days	Indirect (gas pathway)
Silicone tube	External communicating Device, Long term, > 30 days	Indirect (gas pathway)
Sieve bed	External communicating Device, Long term, > 30 days	Indirect (gas pathway)
Oxygen tank	External communicating Device, Long term, > 30 days	Indirect (gas pathway)

8. Substantial Equivalence Discussion

The following table compares the Oxygen Concentrator to the predicate device with respect to indications for use, and technological characteristics, forming the basis for the determination of substantial equivalence. The subject device does not raise any new questions of safety or effectiveness as compared to the predicate device.

Table 5A – Comparison of Characteristics

Characteristics	Subject Device	Predicate Device K061261	Comparison
Device name	oxygen concentrator models 8F-3A/8F-5A	L4 Oxygen Concentrator(EverFlo)	N/A
Classification	2	2	Same
Product Code	CAW	CAW	Same
Regulation Number	21 CFR 868.5440	21 CFR 868.5440	Same
Intended Use	Provide supplemental oxygen	Provide supplemental oxygen	Same
Indication for Use	This oxygen concentrator is intended for using as an oxygen supplement device in the professional healthcare facility and home healthcare environment. It provides high concentration of oxygen to persons requiring oxygen therapy. This device is to be used as an oxygen supplement and is NOT considered life-supporting or life-sustaining.	The Respironics L4 Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining. The Respironics L4 Oxygen Concentrator is intended for use in the home or hospital/institutional environment.	Equivalent
Environment of Use	professional healthcare facility and home healthcare environment.	home or hospital / institutional environment.	Same
IP classification	IP21	IP21	Same
Patient Interface	nasal oxygen cannula	nasal oxygen cannula	Same
Technology	Pressure Swing Adsorption with molecular sieve	Pressure Swing Adsorption with molecular sieve	Same
Oxygen Concentration	(8F-3A): ≥90%; (8F-5A): 95.5%-87%	90-96% from 1 to 5 LPM	Equivalent

Characteristics	Subject Device	Predicate Device K061261	Comparison
Flow Rate	(8F-3A): 1-3 LPM； (8F-5A): 1-5 LPM	from 1 to 5 LPM	Equivalent
Output Pressure	≤70 kPa	44.8 kPa (6.5PSIG)	Equivalent
User Interface	Buttons LCD Display and Indicator light	Buttons LCD Display and Indicator light	Same
Alarms	E 1 low pressure	System malfunction	Similar
	E 2 high pressure		
	E 3 low current		
	E 4 high current		
	Low oxygen concentration alarm	Low oxygen condition（opi unit only）	
	E 5 high temperature inside the device	N/A	
	N/A	high oxygen flow condition	
	LL low flowrate	Low oxygen flow condition	
	Power interrupt alarm	Power interrupt alarm	
Complies with ISO 10993-1	Yes	Yes	Same
Complies with ISO 80601-2-69	Yes	Yes	Same
Complies with ASTM D4169-16	Yes	Yes	Same
Complies with ES 60601-1 Electrical Safety	Yes	Yes	Same

Characteristics	Subject Device	Predicate Device K061261	Comparison
Complies with IEC 60601-1-2 EMC Safety	Yes	Yes	Same

Comparison Discussion Summary:

The Oxygen Concentrator models 8F-3A&8F-5A has the same intended use and the same or similar technological characteristics and functionality as the predicate, the slight differences do not raise new questions of safety and effectiveness as compared to the predicate device.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Oxygen Concentrator models 8F-3A/8F-5A and to show substantial equivalence to the original device, Jiangsu Yuyue Medical Equipment& Supply Co., Ltd completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met. The device passed the testing in accordance with internal requirements, national standards, and international standards shown below, supporting its safety and effectiveness, and its substantial equivalence to the predicate device:

- Electrical safety testing per ES 60601-1
- Electromagnetic Disturbance (EMD) testing per IEC 60601-1-2
- General requirements, tests and guidance for alarm systems per IEC 60601-1-8
- General requirements for basic safety and essential performance in the home healthcare environment per IEC 60601-1-11
- Particular requirements for the basic safety and essential performance of oxygen concentrator equipment per ISO 80601-2-69
- Biocompatibility in gas pathway per ISO 18562-1, ISO 18562-2, ISO 18562-3, ISO 10993-5, ISO 10993-10.
- Software verification and validation per IEC 62304/FDA Guidance – results /conclusion
- Shelf Life Testing – Supports the claimed shelf life
- Transportation Testing per ASTM D4169 – Demonstrates package integrity maintained
- Altitude limit 2000m device performance test
- Accessory compatibility test including connect security, accessory performance

10. Statement of Substantial Equivalence

The Oxygen Concentrator models 8F-3A/8F-5A has the same intended use as the predicate device, and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and effectiveness. Performance testing has demonstrated the Oxygen Concentrator models 8F-3A/8F-5A is as safe and effective as the predicate device. Therefore, the Oxygen Concentrator models 8F-3A/8F-5A is substantially equivalent to the predicate device.