December 29, 2025

Foshan KYCARE Medical Equipment Co., Ltd.
% Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road
Huangpu District
Guangzhou, Guangdong 510530
China

Re: K251534
Trade/Device Name: Oxygen Concentrator (J10A)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: November 27, 2025
Received: November 28, 2025

Dear Cassie Lee:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES J. LEE -S

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

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251534

Please provide the device trade name(s).

Oxygen Concentrator (J10A)

Please provide your Indications for Use below.

The Oxygen Concentrator provide supplemental oxygen to patients who require supplemental O2, 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.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary of K251534

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

1. Submitter's Information

Company Name: Foshan KYCARE Medical Equipment Co., Ltd.
Address: Room 401, Building 29, Liandong Yougu Park, No 3, Dongsan District, Jiansha Road, Danzao Town, Nanhai District, Foshan City, Guangdong Province, China
Contact Person (including title): Leona Zhou (Regulatory Affair Manager)
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Application Correspondent:
Contact Person: Ms. Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel : +86 20 8266 2446
Email : 382198657@qq.com

2. Subject Device Information:

Type of 510(k): Traditional
Common Name: Portable Oxygen Concentrator
Classification Name: Generator, Oxygen, Portable
Trade Name: Oxygen Concentrator
Model Name: J10A
Review Panel: Anesthesiology
Product Code: CAW
Regulation Number: 868.5440
Regulatory Class: II

3. Predicate Device Information

Sponsor: FOSHAN CARE MEDICAL TECHNOLOGY CO., LTD.
Trade Name: Oxygen Concentrator
Model Name: ZY-10AB/115
Classfication Name: Generator, Oxygen, Protable
510(k) Number: K240840
Review Panel: Anesthesiology
Product Code: CAW
Regulation Number: 868.5440
Regulatory Class: II

4. Device Description

The Oxygen Concentrator 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 device could provide approximately 90~96% of oxygen to patients on a continuous flow basis at a rate of 1L/min to 10L/min. The nasal cannula is not sold with the device, users need to purchase the accessories by themselves that are legally marketed. The products have not undergone biocompatibility assessment of condensate precipitates according to ISO18562-4, and it is not recommended to use humidification bottles.
The maximum altitude the subject device can operate without degradation of concentration is 2000m.

The predicate device ZY-10AB/115 is the original device of subject device J10A, just different in the model name and the information of the 510k sponsor.

5. Intended Use / Indications for Use

The Oxygen Concentrator provide supplemental oxygen to patients who require supplemental O2, 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. Intended patient population

- Population: adult
- Age: above 18 years old
- Health status: adult patients requiring supplemental oxygen.

7. Comparison to predicate devices

Elements of Comparison	Subject Device	Predicate Device	Verdict
Company	Foshan KYCARE Medical Equipment Co., Ltd.	FOSHAN CARE MEDICAL TECHNOLOGY CO., LTD.	--
Trade Name	Oxygen Concentrator	Oxygen Concentrator	--
Model	J10A	ZY-10AB/115	--
Classification Name	Generator, Oxygen, Portable	Generator, Oxygen, Portable	Same
510(k) Number	K251534	K240840	--
Product Code	CAW	CAW	Same
Intended Use / Indications for Use	The Oxygen Concentrator provide supplemental oxygen to patients who require supplemental O_2, 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 Oxygen Concentrator provide supplemental oxygen to patients who require supplemental O_2, 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.	Same
Work principle	Pressure swing adsorption principle, filtering by molecular sieve	Pressure swing adsorption principle, filtering by molecular sieve	Same
Working mode	Continuous	Continuous	Same
Environments of Use	Home or health care facility	Home or health care facility	Same
Intended patient population	• Population: adult • Age: above 18 years old • Health status: adult patients requiring supplemental oxygen.	• Population: adult • Age: above 18 years old • Health status: adult patients requiring supplemental oxygen.	Same
Performance Comparison			
Power supply	AC 100-120V, 60Hz	AC 100-120V, 60Hz	Same
Max.Input power	550VA	550VA	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
Oxygen concentration	93% ± 3%	93% ± 3%	Same
Oxygen flow	1-10L/min	1-10L/min	Same
Outlet pressure	40kPa-80kPa	40kPa-80kPa	Same
Noise	≤60dB (A) under max. flowrate	≤60dB (A) under max. flowrate	Same
Electrical classification	Class II Type BF	Class II Type BF	Same
Alarm	Low Oxygen purity; Low & high pressure; Power loss alarm; Oxygen Sensor failure; Flow rate less than 0.4L/Min; Display Circuit Board failure	Low Oxygen purity; Low & high pressure; Power loss alarm; Oxygen Sensor failure; Flow rate less than 0.4L/Min; Display Circuit Board failure	Same
Oxygen concentration warning	<82%, indicator yellow light and medium Blinking (0.4Hz-0.8Hz), auditory signal: Di-Di-Di 16±1 seconds interval and display error code “E2”; <73%±3%, indicator red light and fast Blinking (0.4Hz-0.8Hz), auditory signal: Di-Di-Di----Di-Di 4±1 seconds interval and display error code “E1”	<82%, indicator yellow light and medium Blinking (0.4Hz-0.8Hz), auditory signal: Di-Di-Di 16±1 seconds interval and display error code “E2”; <73%±3%, indicator red light and fast Blinking (0.4Hz-0.8Hz), auditory signal: Di-Di-Di----Di-Di 4±1 seconds interval and display error code “E1”	Same
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	Running time; Accumulating timing	Running time; Accumulating timing	Same
Accessories	manual	manual	Same
Dimensions	620 x 370 x 345mm	620 x 370 x 345mm	Same
Safety Comparison			
Sieve Bed	Synthetic Zeolite	Synthetic Zeolite	Same
Biocompatibility of materials contacting user	ISO 18562-2:2017, ISO 18562-3:2017	ISO 18562-2:2017, ISO 18562-3:2017	Same
EMC	Comply with IEC 60601-1-2:2014+A1:2020	Comply with IEC 60601-1-2:2014+A1:2020	Same
Electric safety	Comply with IEC 60601-1-11:2015/AMD1:2020, ISO 80601-2-69:2014, IEC 80601-1-8:2020 IEC 60601-1:2005/AMD2:2020	Comply with IEC 60601-1-11:2015/AMD1:2020, ISO 80601-2-69:2014, IEC 80601-1-8:2020 IEC 60601-1:2005/AMD2:2020	Same

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test
Electrical safety and EMC testing were conducted on the proposed device. The device was shown to comply with IEC 60601-1-2:2020 and IEC TR 60601-4-2:2016 for electromagnetic compatibility, IEC 60601-1:2020, IEC 60601-1-8:2012, IEC 60601-1-11:2020 and ISO 80601-2-69:2020 for electrical safety.

2) Biocompatibility Test
Biocompatibility testing was performed on the subject device components in accordance with FDA guidance document entitled "Use of international Standard ISO 18562-1, "Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications- Part 1: Evaluation and Testing within a Risk Management Process." The device was shown to comply with ISO 18562-2 and ISO 18562-3.

3) Software verification and validation
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Usability validation
Usability evaluation was conducted and documented according to the recognized consensus standards of IEC 62366-1 and IEC 60601-6. The result of the usability demonstrated all the users in testing did not show any critical errors and represented the performance of using can be smoother by extra practices without specific usability problems. The device has been found to be reasonably safe and effective for the intended users, uses and uses environments.

5) Cybersecurity

The subject device no external interfaces, according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", no need cybersecurity evaluation.

7.2 Summary of Clinical Performance
Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

8. Date of the summary prepared: November 27, 2025

9. <u>Final Conclusion</u>
The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K240840.