

**K251534 Oxygen Concentrator (J10A)**Dec 29, 2025  
224 days to decisionK251534 · Product code: **CAW** · Anesthesiology  
Source: <https://www.510kdatabase.net/k251534/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	May 19, 2025
Decision date	Dec 29, 2025
Days to decision	224 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Foshan Kycare Medical Equipment Co., Ltd.</b>
Location	Foshan, CN
Contact	Leona Zhou
510(k) history	2 submissions · 2 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Share Info (Guangzhou) Medical Consultant , Ltd.</b>
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251534/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026