

**K243833 Portable oxygen concentrator (JAY-1000P)**Sep 29, 2025  
290 days to decisionK243833 · Product code: **CAW** · Anesthesiology  
Source: <https://www.510kdatabase.net/k243833/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Dec 13, 2024
Decision date	Sep 29, 2025
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Longfian Scitech Co., Ltd.</b>
Location	Miami, FL, US
Contact	Lei Shi
510(k) history	3 submissions · 3 cleared · 2014-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai SUNGO Management Consulting Co., Ltd.</b>
Contact	Ivy Wang

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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243833/> 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