

**K242736 Portable Oxygen Concentrator (Spirit-3)**Jun 5, 2025  
267 days to decisionK242736 · Product code: **CAW** · Anesthesiology  
Source: <https://www.510kdatabase.net/k242736/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Sep 11, 2024
Decision date	Jun 5, 2025
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Yuyue Medical Equipment&amp; Supply Co., Ltd.</b>
Location	Zhenjiang, CN
Contact	Yan Wei
510(k) history	14 submissions · 14 cleared · 2009-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Qimmiq Medical Consulting Service Co., Ltd.</b>
Contact	Yijie You

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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