

K250625 Portable oxygen concentrator (W-R1(MAX))Aug 27, 2025
177 days to decisionK250625 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k250625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Mar 3, 2025
Decision date	Aug 27, 2025
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Portable oxygen concentrator (W-R1); Portable oxygen concentrator (W-R2); Portable oxygen concentrator (W-R2(Lite))

APPLICANT

Company	Nanjing Yinuoji Medical Technology Co., Ltd.
Location	Nanjing, CN
Contact	Xiao Xu
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Imangel Consulting, Inc.
Contact	Jerry Sudduth

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.netDevice record: <https://www.510kdatabase.net/k250625/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026