

K213825 Oxygen Concentrator model 8F-3A, Oxygen Concentrator model 8F-5AApr 28, 2023
506 days to decisionK213825 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k213825/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Dec 8, 2021
Decision date	Apr 28, 2023
Days to decision	506 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213825/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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