

K250671 FreeStyle Comfort (AS200 / FreeStyle Comfort)Jul 11, 2025
128 days to decisionK250671 · Product code: **CAW** · Anesthesiology
Source: <https://www.510kdatabase.net/k250671/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Mar 5, 2025
Decision date	Jul 11, 2025
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Caire, Inc.
Location	Littleton, CO, US
Contact	Ted Vlahopoulos
510(k) history	7 submissions · 7 cleared · 1995-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250671/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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