

**K230915 AirLife™ Open Et Oxygen Mask, AirLife™ Open Et+ Oxygen Mask**Nov 12, 2024  
592 days to decisionK230915 · Product code: **CCK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k230915/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Gas, Carbon-dioxide, Gaseous-phase (CCK)
Date received	Mar 31, 2023
Decision date	Nov 12, 2024
Days to decision	592 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Vyaire Medical, Inc.</b>
Location	Helsinki, FI
Contact	Naila Bukhari
510(k) history	9 submissions · 9 cleared · 2018-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230915/> 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