

K133360 AERONEB SOLOOct 17, 2014
350 days to decisionK133360 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k133360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 1, 2013
Decision date	Oct 17, 2014
Days to decision	350 days
Third-party review	No
Summary / Statement	Summary
Other names	AERONEB SOLO ADAPTER

APPLICANT

Company	Aerogen, Ltd.
Location	Galway, IE
Contact	MARTIN CREHAN
510(k) history	5 submissions · 5 cleared · 2011-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k133360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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