

K201167 AireHealth NebulizerTMDec 3, 2020
216 days to decisionK201167 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k201167/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	May 1, 2020
Decision date	Dec 3, 2020
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Airehealth, Inc.
Location	Orlando, FL, US
Contact	Rusty Kelly
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Regulatory and Quality Solutions, LLC
Contact	Jessica Czamanski

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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