

K203155 BreatheSuite MDI V1Sep 17, 2021
330 days to decisionK203155 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k203155/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Oct 22, 2020
Decision date	Sep 17, 2021
Days to decision	330 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Breathesuite, Inc.
Location	St. John's, CA
Contact	Brett Vokey
510(k) history	1 submissions · 1 cleared · 2021-2021

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