

K200063 AeroEclipse* ONE BANJul 17, 2020
186 days to decisionK200063 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k200063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jan 13, 2020
Decision date	Jul 17, 2020
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trudell Medical International
Location	London, CA
Contact	Marianne Tanton
510(k) history	9 submissions · 9 cleared · 2015-2025

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