

K180407 SmartinhalerJul 25, 2018
161 days to decisionK180407 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k180407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Feb 14, 2018
Decision date	Jul 25, 2018
Days to decision	161 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Adherium (Nz), Ltd.
Location	Auckland, NZ
Contact	Chris Mander
510(k) history	10 submissions · 10 cleared · 2017-2023

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