

K182638 Hailie SensorJun 19, 2019
268 days to decisionK182638 · Product code: **CAF** · Anesthesiology
Source: <https://www.510kdatabase.net/k182638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Sep 24, 2018
Decision date	Jun 19, 2019
Days to decision	268 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026