

**K221994 Hailie Sensor NF0107 & NF0108**Oct 4, 2022  
90 days to decisionK221994 · Product code: **CAF** · AnesthesiologySource: <https://www.510kdatabase.net/k221994/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jul 6, 2022
Decision date	Oct 4, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Adherium (Nz), Ltd.</b>
Location	Auckland, NZ
Contact	Tara Creaven-Capasso
510(k) history	10 submissions · 10 cleared · 2017-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221994/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026