

**K122857 HOPE CONTINUOUS NEBULIZER MODEL  
HOPE-11310, HEART NEBULIZER MODEL HEART-100609,  
THERAMIST NEBULIZER MODEL THERAMIST-3100**Nov 7, 2012  
50 days to decisionK122857 · Product code: **CAF** · Anesthesiology  
Source: <https://www.510kdatabase.net/k122857/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Sep 18, 2012
Decision date	Nov 7, 2012
Days to decision	50 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pegasus Research Corp.</b>
Location	Corona Del Mar, CA, US
Contact	KENNETH MILLER
510(k) history	12 submissions · 12 cleared · 1988-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122857/> 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 24, 2026