

**K140124 S9 ELOUERA**May 12, 2014  
116 days to decisionK140124 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k140124/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Jan 16, 2014
Decision date	May 12, 2014
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>ResMed Corp</b>
Location	Poway, CA, US
Contact	JIM CASSI
Website	<a href="http://www.resmed.com/">http://www.resmed.com/</a>
510(k) history	15 submissions · 15 cleared · 1997-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140124/>; 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 25, 2026