

K082979 S8 ADVANCEJan 2, 2009
88 days to decisionK082979 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k082979/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Oct 6, 2008
Decision date	Jan 2, 2009
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Resmed, Ltd.
Location	Poway, CA, US
Contact	DAVID D'AMICO; CRUZ
Website	http://www.resmed.com/
510(k) history	103 submissions · 103 cleared · 1996-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082979/>; 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 June 19, 2026