

K253553 OrionJun 4, 2026
202 days to decisionK253553 · Product code: **BZD** · AnesthesiologySource: <https://www.510kdatabase.net/k253553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Nov 14, 2025
Decision date	Jun 4, 2026
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ResMed Corp
Location	Poway, CA, US
Contact	Prerana Gurubasavaraj
Website	http://www.resmed.com/
510(k) history	17 submissions · 17 cleared · 1997-2026

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