

K251657 Personalized Therapy Comfort Settings (PTCS)Dec 5, 2025
189 days to decisionK251657 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k251657/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	May 30, 2025
Decision date	Dec 5, 2025
Days to decision	189 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ResMed Corp
Location	Poway, CA, US
Contact	Rose Malonzo
Website	http://www.resmed.com/
510(k) history	15 submissions · 15 cleared · 1997-2026

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