

K203126 S10 KirraDec 18, 2020
60 days to decisionK203126 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k203126/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Oct 19, 2020
Decision date	Dec 18, 2020
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Resmed Pty , Ltd.
Location	Bella Vista, AU
Contact	Peter Jennings
510(k) history	3 submissions · 3 cleared · 2020-2026

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