

K200565 GalapogosJan 17, 2021
319 days to decisionK200565 · Product code: **BZD** · Anesthesiology
Source: <https://www.510kdatabase.net/k200565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Mar 4, 2020
Decision date	Jan 17, 2021
Days to decision	319 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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