FDA 510(k) Premarket Notification

K112393 TASMAN

CLEARED

Nov 16, 2011
89 days to decision

K112393 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k112393/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Aug 19, 2011
Decision date	Nov 16, 2011
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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