FDA 510(k) Premarket Notification

K090490 MIRAGE ECHO

CLEARED

May 6, 2009
70 days to decision

K090490 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k090490/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Feb 25, 2009
Decision date	May 6, 2009
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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