FDA 510(k) Premarket Notification

K013843 AUTOSET SPIRIT CPAP SYSTEM

CLEARED

Jul 16, 2002
238 days to decision

K013843 · Product code: **BZD** · Anesthesiology
Source: https://www.510kdatabase.net/k013843/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Nov 20, 2001
Decision date	Jul 16, 2002
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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