FDA 510(k) Premarket Notification

K131932 APNEALINK PRO

CLEARED

Nov 8, 2013
134 days to decision

K131932 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k131932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jun 27, 2013
Decision date	Nov 8, 2013
Days to decision	134 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Resmed Germany, Inc.**
Location	Poway, CA, US
Contact	SANDRA GRUNWALD
510(k) history	8 submissions · 8 cleared · 2006-2015