FDA 510(k) Premarket Notification

K112514 APNEA RISK EVALUATION SYSTEM (ARES)

CLEARED

Jan 9, 2012
132 days to decision

K112514 · Product code: **MNR** · Anesthesiology
Source: https://www.510kdatabase.net/k112514/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Aug 30, 2011
Decision date	Jan 9, 2012
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Advanced Brain Monitoring, Inc.**
Location	Carlsbad, CA, US
Contact	ADRIENNE LENZ
510(k) history	14 submissions · 14 cleared · 2004-2016