

K213360 SleepCheckRxJul 5, 2022
266 days to decisionK213360 · Product code: **MNR** · Anesthesiology
Source: <https://www.510kdatabase.net/k213360/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Oct 12, 2021
Decision date	Jul 5, 2022
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Resapp Health
Location	Brisbane, AU
Contact	Neroli Anderson
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213360/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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