

K231546 SomfitNov 30, 2023
184 days to decisionK231546 · Product code: **MNR** · Neurology
Source: <https://www.510kdatabase.net/k231546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	May 30, 2023
Decision date	Nov 30, 2023
Days to decision	184 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Compumedics Limited
Location	Minneapolis,, MN, US
Contact	Michael Frischman
510(k) history	9 submissions · 9 cleared · 2000-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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