

K252383 Somfit DAug 28, 2025
28 days to decisionK252383 · Product code: **MNR** · Neurology
Source: <https://www.510kdatabase.net/k252383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jul 31, 2025
Decision date	Aug 28, 2025
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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