

**K243513 DCM (PW-DCM)**Apr 16, 2025  
155 days to decisionK243513 · Product code: **LEL** · Neurology  
Source: <https://www.510kdatabase.net/k243513/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Sleep Assessment (LEL)
Date received	Nov 12, 2024
Decision date	Apr 16, 2025
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Pneumowave, Ltd.</b>
Location	Eurocentral, GB
Contact	Stuart Kelly
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243513/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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