

**K230148 Vlab**Oct 11, 2023  
265 days to decisionK230148 · Product code: **GWL** · Neurology  
Source: <https://www.510kdatabase.net/k230148/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplifier, Physiological Signal (GWL)
Date received	Jan 19, 2023
Decision date	Oct 11, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dormotech Medical, Ltd.</b>
Location	Afula, IL
Contact	Abed Nassir
510(k) history	2 submissions · 2 cleared · 2023-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedic Consulting, LLC</b>
Contact	Paul Dryden

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

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