FDA 510(k) Premarket Notification

K230148 Vlab

CLEARED

Oct 11, 2023
265 days to decision

K230148 · Product code: **GWL** · Neurology
Source: https://www.510kdatabase.net/k230148/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**ProMedic Consulting, LLC**
Contact	Paul Dryden

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