

K243746 Delphi AmplifierMar 12, 2025
97 days to decisionK243746 · Product code: **GWL** · Neurology
Source: <https://www.510kdatabase.net/k243746/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplifier, Physiological Signal (GWL)
Date received	Dec 5, 2024
Decision date	Mar 12, 2025
Days to decision	97 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quantalx Neroscience
Location	Kfar Sava, IL
Contact	Iftach Dolev
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	ProMedoss, Inc.
Contact	Bosmat Friedman-Cox

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

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