

**K242345 Delphi Stimulator**Nov 5, 2024  
90 days to decisionK242345 · Product code: **GWF** · Neurology  
Source: <https://www.510kdatabase.net/k242345/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Evoked Response (GWF)
Date received	Aug 7, 2024
Decision date	Nov 5, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Quantalx Neuroscience</b>
Location	Kfar Sava, IL
Contact	Iftach Dolev
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedoss, Inc.</b>
Contact	Bosmat Friedman-Cox

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242345/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026