

K243243 Delphi MCS Electrode CapFeb 6, 2025
118 days to decisionK243243 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k243243/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Oct 11, 2024
Decision date	Feb 6, 2025
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quantalx Neuroscience, Ltd.
Location	Kfar Sava, IL
Contact	Hlila Fogel
510(k) history	2 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](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243243/> Data sourced from FDA 510(k) public records (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. - Generated May 13, 2026