

K232210 X-trodes System MFeb 4, 2024
193 days to decisionK232210 · Product code: **GWL** · Neurology
Source: <https://www.510kdatabase.net/k232210/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amplifier, Physiological Signal (GWL)
Date received	Jul 26, 2023
Decision date	Feb 4, 2024
Days to decision	193 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	X-Trodes
Location	Herzeliya, IL
Contact	Ziv Peremen
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group
Contact	Donna-Bea Tillman

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/k232210/> 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 14, 2026