

**K220254 Neuron-Spectrum-AM with Neuron-Spectrum.NET Software**Nov 30, 2022  
303 days to decisionK220254 · Product code: **OLT** · Neurology  
Source: <https://www.510kdatabase.net/k220254/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-normalizing Quantitative Electroencephalograph Software (OLT)
Date received	Jan 31, 2022
Decision date	Nov 30, 2022
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neurosoft , Ltd.</b>
Location	Abano Terme, Padova, IT
Contact	Michael Durdin
510(k) history	3 submissions · 3 cleared · 2015-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Corticare, Inc.</b>
Contact	Vicki Chester

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/k220254/>; 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 25, 2026