

**K250601 Neuro Omega System**Mar 30, 2025  
30 days to decisionK250601 · Product code: **GZL** · Neurology  
Source: <https://www.510kdatabase.net/k250601/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Depth (GZL)
Date received	Feb 28, 2025
Decision date	Mar 30, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NeuroSmart System

**APPLICANT**

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Company	<b>Alpha Omega Engineering , Ltd.</b>
Location	Nazareth Illit, IL
Contact	Efrat Shamgar
510(k) history	8 submissions · 8 cleared · 2006-2025

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