

K220553 Neuro Omega System, NeuroSmart SystemSep 16, 2022
200 days to decisionK220553 · Product code: **GZL** · Neurology
Source: <https://www.510kdatabase.net/k220553/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Depth (GZL)
Date received	Feb 28, 2022
Decision date	Sep 16, 2022
Days to decision	200 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220553/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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