

K171581 Neuro Omega SystemDec 22, 2017
205 days to decisionK171581 · Product code: **GZL** · Neurology
Source: <https://www.510kdatabase.net/k171581/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrode, Depth (GZL) |
| Date received | May 31, 2017 |
| Decision date | Dec 22, 2017 |
| Days to decision | 205 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k171581/> 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 26, 2026