

K191739 Sterile LeadConfirmJan 2, 2020
188 days to decisionK191739 · Product code: **GZL** · Neurology
Source: <https://www.510kdatabase.net/k191739/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	Jun 28, 2019
Decision date	Jan 2, 2020
Days to decision	188 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

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