

K211367 Evo sEEG SystemSep 1, 2021
120 days to decisionK211367 · Product code: **GZL** · Neurology
Source: <https://www.510kdatabase.net/k211367/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	May 4, 2021
Decision date	Sep 1, 2021
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neuroone Medical Technologies Corp.
Location	Eden Prairie, MN, US
Contact	Joseph Ostendorf
510(k) history	4 submissions · 4 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Ostendorf Consulting, LLC
Contact	Joseph Ostendorf

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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