

K253970 Wovyn Depth ElectrodeApr 17, 2026
127 days to decisionK253970 · Product code: **GZL** · Neurology
Source: <https://www.510kdatabase.net/k253970/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Depth (GZL)
Date received	Dec 11, 2025
Decision date	Apr 17, 2026
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sensomedical Labs, Ltd.
Location	Nazareth, IL
Contact	Maroun Farah
510(k) history	2 submissions · 2 cleared · 2023-2026

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