FDA 510(k) Premarket Notification

K250239 NeuroMatch

CLEARED

May 23, 2025
116 days to decision

K250239 · Product code: **OLX** · Neurology
Source: https://www.510kdatabase.net/k250239/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Source Localization Software For Electroencephalograph Or Magnetoencephalograph (OLX)
Date received	Jan 27, 2025
Decision date	May 23, 2025
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**LVIS Corporation**
Location	Palo Alto, CA, US
Contact	Sweta Srivastava
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Sweta Srivastava

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

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Device record: https://www.510kdatabase.net/k250239/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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