FDA 510(k) Premarket Notification

K222450 LVIS NeuroMatch

CLEARED

Jun 9, 2023
298 days to decision

K222450 · Product code: **OMB** · Neurology
Source: https://www.510kdatabase.net/k222450/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automatic Event Detection Software For Full-montage Electroencephalograph (OMB)
Date received	Aug 15, 2022
Decision date	Jun 9, 2023
Days to decision	298 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Veranex, Inc.**
Contact	Zane Liu

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