

K240420 NeuroField Analysis SuiteSep 20, 2024
220 days to decisionK240420 · Product code: **OLU** · Neurology
Source: <https://www.510kdatabase.net/k240420/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Normalizing Quantitative Electroencephalograph Software (OLU)
Date received	Feb 13, 2024
Decision date	Sep 20, 2024
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurofield, Inc.
Location	Bishop, CA, US
Contact	Nicholas Dogris
510(k) history	3 submissions · 3 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	Vision28
Contact	Tom Renner

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

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