

K221959 Q21Aug 31, 2023
422 days to decisionK221959 · Product code: **GWQ** · Neurology
Source: <https://www.510kdatabase.net/k221959/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Full-montage Standard Electroencephalograph (GWQ)
Date received	Jul 5, 2022
Decision date	Aug 31, 2023
Days to decision	422 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurofield, Inc.
Location	Bishop, CA, US
Contact	Nicholas J. 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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