

K243426 Nurochek-Pro SystemMar 27, 2025
143 days to decisionK243426 · Product code: **PIW** · Neurology
Source: <https://www.510kdatabase.net/k243426/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid (PIW)
Date received	Nov 4, 2024
Decision date	Mar 27, 2025
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Headsafe Mfg Pty, Ltd.
Location	Surry Hills, AU
Contact	Dylan Mahony
510(k) history	2 submissions · 2 cleared · 2023-2025

REGULATORY CONSULTANT

Consulting firm	RQM+
Contact	Erin Gontang

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243426/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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