

**K231914 Nurochek-II System**Dec 27, 2023  
181 days to decisionK231914 · Product code: **PIW** · Neurology  
Source: <https://www.510kdatabase.net/k231914/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Brain Injury Adjunctive Interpretive Electroencephalograph Assessment Aid (PIW)
Date received	Jun 29, 2023
Decision date	Dec 27, 2023
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Headsafe Mfg Pty, Ltd.</b>
Location	Surry Hills, AU
Contact	Adrian Cohen
510(k) history	2 submissions · 2 cleared · 2023-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>RQM+</b>
Contact	Erin Gontang

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231914/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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