FDA 510(k) Premarket Notification

K231914 Nurochek-II System

CLEARED

Dec 27, 2023
181 days to decision

K231914 · Product code: **PIW** · Neurology
Source: https://www.510kdatabase.net/k231914/

SUBMISSION DETAILS

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

Company	**Headsafe Mfg Pty, Ltd.**
Location	Surry Hills, AU
Contact	Adrian Cohen
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