

**K253015 Cognitive Function Neuroimaging (cfNI) Software
(1.0.0)**Jun 12, 2026
266 days to decisionK253015 · Product code: **OLU** · Neurology
Source: <https://www.510kdatabase.net/k253015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Normalizing Quantitative Electroencephalograph Software (OLU)
Date received	Sep 19, 2025
Decision date	Jun 12, 2026
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	VoxNeuro, Inc.
Location	Toronto, CA
Contact	Andrew Matiasso
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253015/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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