

K213299 Wireless EEG SystemMay 11, 2022
222 days to decisionK213299 · Product code: **OLT** · Neurology
Source: <https://www.510kdatabase.net/k213299/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Non-normalizing Quantitative Electroencephalograph Software (OLT)
Date received	Oct 1, 2021
Decision date	May 11, 2022
Days to decision	222 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pascall Systems, Inc.
Location	Boston, MA, US
Contact	Tuan Le Mau
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Steurer Consulting Group
Contact	Robert Steurer

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/k213299/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026