

K011204 NEUROFAX, MODELS EEG-1100A, EEG-9100AMay 8, 2001
19 days to decisionK011204 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k011204/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Apr 19, 2001
Decision date	May 8, 2001
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nihon Kohden America, Inc.
Location	Foothill Ranch, CA, US
Contact	BONNIE BISHOP
510(k) history	166 submissions · 163 cleared · 1979-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011204/> 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 24, 2026