

K000338 VITAPORT 3Apr 26, 2000
83 days to decisionK000338 · Product code: **OLV** · Neurology
Source: <https://www.510kdatabase.net/k000338/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Feb 3, 2000
Decision date	Apr 26, 2000
Days to decision	83 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/k000338/> 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