

**K033475 WIRELESS INPUT UNIT, MODEL WEE-1000A SERIES**Jan 7, 2004  
65 days to decisionK033475 · Product code: **OLV** · Neurology  
Source: <https://www.510kdatabase.net/k033475/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	Nov 3, 2003
Decision date	Jan 7, 2004
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Nihon Kohden America, Inc.</b>
Location	Foothill Ranch, CA, US
Contact	SERRAH NAMINI
510(k) history	166 submissions · 163 cleared · 1979-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033475/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 24, 2026