

**K971867 ALICE 4R SYSTEM**Aug 13, 1997  
85 days to decisionK971867 · Product code: **OLV** · Neurology  
Source: <https://www.510kdatabase.net/k971867/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Standard Polysomnograph With Electroencephalograph (OLV)
Date received	May 20, 1997
Decision date	Aug 13, 1997
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Healthdyne Technologies, Inc.</b>
Location	Marietta, GA, US
Contact	TIMOTHY Y COWART
510(k) history	9 submissions · 9 cleared · 1994-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971867/> 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 26, 2026