

**K924429 OPUS(R) CK-MB**Oct 15, 1992  
44 days to decisionK924429 · Product code: **JHY** · Toxicology  
Source: <https://www.510kdatabase.net/k924429/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Sep 1, 1992
Decision date	Oct 15, 1992
Days to decision	44 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pb Diagnostic Systems, Inc.</b>
Location	Westwood, MA, US
Contact	NANC M JOHANSEN
510(k) history	35 submissions · 35 cleared · 1988-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k924429/> 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 June 29, 2026