

**K896868 OPUS PHENYTOIN TEST SYSTEM**Jan 2, 1990  
26 days to decisionK896868 · Product code: **LGR** · Toxicology  
Source: <https://www.510kdatabase.net/k896868/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescence Polarization Immunoassay, Diphenylhydantoin (total) (LGR)
Date received	Dec 7, 1989
Decision date	Jan 2, 1990
Days to decision	26 days
Third-party review	No

**APPLICANT**

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Company	<b>Pb Diagnostic Systems, Inc.</b>
Location	Westwood, MA, US
Contact	LORI BARANAUSKAS
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/k896868/>; 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