

**K915345 STAT K SYSTEM**Jul 16, 1992  
233 days to decisionK915345 · Product code: **CEM** · Chemistry  
Source: <https://www.510kdatabase.net/k915345/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Ion Specific, Potassium (CEM)
Date received	Nov 26, 1991
Decision date	Jul 16, 1992
Days to decision	233 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Portable Diagnostic Services, Inc.</b>
Location	Westlake Village, CA, US
Contact	GERARD J PUTZ
510(k) history	1 submissions · 1 cleared · 1992-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915345/> 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 July 2, 2026