

**K971566 CREATINE KINASE-MB REAGENT SET**Jul 14, 1997  
76 days to decisionK971566 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k971566/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS)
Date received	Apr 29, 1997
Decision date	Jul 14, 1997
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Horizon Diagnostics, Inc.</b>
Location	Jackson, MI, US
Contact	DAVID L CALLENDER
510(k) history	7 submissions · 7 cleared · 1993-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k971566/> 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 30, 2026