

**K891050 STAT CHEM SYSTEM**Jul 20, 1989  
142 days to decisionK891050 · Product code: **CGA** · Chemistry  
Source: <https://www.510kdatabase.net/k891050/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Oxidase, Glucose (CGA)
Date received	Feb 28, 1989
Decision date	Jul 20, 1989
Days to decision	142 days
Third-party review	No

**APPLICANT**

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Company	<b>Diagnostic Resources, Inc.</b>
Location	Walker, MI, US
Contact	RINALDO PAGNUCCO,PHD
510(k) history	4 submissions · 4 cleared · 1981-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k891050/>, 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