

**K963534 SIGMA DIAGNOSTICS CREATININE REAGENT KIT**Sep 30, 1996  
26 days to decisionK963534 · Product code: **CGX** · Chemistry  
Source: <https://www.510kdatabase.net/k963534/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Sep 4, 1996
Decision date	Sep 30, 1996
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963534/> 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 May 14, 2026