

**K923203 SYSTEMATE CREATININE TEST**Sep 9, 1992  
76 days to decisionK923203 · Product code: **CGX** · Chemistry  
Source: <https://www.510kdatabase.net/k923203/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alkaline Picrate, Colorimetry, Creatinine (CGX)
Date received	Jun 25, 1992
Decision date	Sep 9, 1992
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Em Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
Contact	CAROL FAULKNER
510(k) history	288 submissions · 288 cleared · 1984-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k923203/> 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