

**K932160 SYSTEMATE CREATININE TEST ITEM NUMBER 65413**Jul 9, 1993  
66 days to decisionK932160 · Product code: **CGX** · Chemistry  
Source: <https://www.510kdatabase.net/k932160/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Alkaline Picrate, Colorimetry, Creatinine (CGX) |
| Date received         | May 4, 1993                                     |
| Decision date         | Jul 9, 1993                                     |
| Days to decision      | 66 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/k932160/> 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