

**K895119 SYSTEMATE DIRECT BILIRUBIN CATALOG NO. 65406**Oct 17, 1989  
63 days to decisionK895119 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k895119/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Diazo Colorimetry, Bilirubin (CIG) |
| Date received         | Aug 15, 1989                       |
| Decision date         | Oct 17, 1989                       |
| Days to decision      | 63 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Em Diagnostic Systems, Inc.</b>        |
| Location       | Walker, MI, US                            |
| Contact        | ANNA BENTLEY                              |
| 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/k895119/>; 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