

**K902123 SYSTEMATE(TM) DIRECT BILIRUBIN CATALOG NO.
65406**Jun 6, 1990
26 days to decisionK902123 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k902123/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	May 11, 1990
Decision date	Jun 6, 1990
Days to decision	26 days
Third-party review	No

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	G BENTLEY
510(k) history	288 submissions · 288 cleared · 1984-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k902123/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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