

**K922856 SYSTEMATE DIRECT BILIRUBIN TEST TECHNICON  
RA 1000**Sep 9, 1992  
86 days to decisionK922856 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k922856/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jun 15, 1992
Decision date	Sep 9, 1992
Days to decision	86 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/k922856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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