

**K897176 SYSTEMATE(TM) TOTAL BILIRUBIN CATALOG NO.  
654XX**Mar 19, 1990  
82 days to decisionK897176 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k897176/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Dec 27, 1989
Decision date	Mar 19, 1990
Days to decision	82 days
Third-party review	No

**APPLICANT**

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Company	<b>Em Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
Contact	ANNA G 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/k897176/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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