

**K850128 SYSTE MATE TIBC HEM NO. 67225**Feb 1, 1985  
18 days to decisionK850128 · Product code: **JMO** · Chemistry  
Source: <https://www.510kdatabase.net/k850128/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ferrozine (colorimetric) Iron Binding Capacity (JMO)
Date received	Jan 14, 1985
Decision date	Feb 1, 1985
Days to decision	18 days
Third-party review	No

**APPLICANT**

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Company	<b>Em Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
Contact	RAYMOND L MILLER
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/k850128/>; 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