

**K860764 EMDS ENZYME VERIFIER, LEVELS I & II**Apr 7, 1986  
35 days to decisionK860764 · Product code: **JJT** · Chemistry  
Source: <https://www.510kdatabase.net/k860764/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Mar 3, 1986
Decision date	Apr 7, 1986
Days to decision	35 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/k860764/>; 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