

**K861512 EMDS, CK/CK-MB VERIFIER, ITEM NUMBER 67---/95**May 23, 1986  
30 days to decisionK861512 · Product code: **JJT** · Chemistry  
Source: <https://www.510kdatabase.net/k861512/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Apr 23, 1986
Decision date	May 23, 1986
Days to decision	30 days
Third-party review	No

**APPLICANT**

---

Company	<b>Em Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
Contact	RAYMOND L MILLER
510(k) history	288 submissions · 288 cleared · 1984-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861512/>; 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