

**K884549 ALKALINE PHOSPHATASE TEST (ALP) ITEM NO.  
65651**Nov 10, 1988  
10 days to decisionK884549 · Product code: **CJE** · Chemistry  
Source: <https://www.510kdatabase.net/k884549/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Oct 31, 1988
Decision date	Nov 10, 1988
Days to decision	10 days
Third-party review	No

**APPLICANT**

---

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

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884549/>; 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