

**K884376 ALANINE AMINOTRANSFERASE TEST ITEM NO.
65652**

Jan 11, 1989
85 days to decision

K884376 · Product code: **CKA** · Chemistry
Source: <https://www.510kdatabase.net/k884376/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Alt/sgpt (CKA)
Date received	Oct 18, 1988
Decision date	Jan 11, 1989
Days to decision	85 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k884376/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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