

**K884377 ASPARTATE AMINOTRANSFERASE TEST ITEM NO.
65654**Dec 14, 1988
57 days to decisionK884377 · Product code: **CIT** · Chemistry
Source: <https://www.510kdatabase.net/k884377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Ast/sgot (CIT)
Date received	Oct 18, 1988
Decision date	Dec 14, 1988
Days to decision	57 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.netDevice record: <https://www.510kdatabase.net/k884377/>; Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026