

K884382 AMYLASE TEST (AMYL) ITEM NUMBER: 65653Jan 11, 1989
85 days to decisionK884382 · Product code: **CIW** · Chemistry
Source: <https://www.510kdatabase.net/k884382/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Starch-dye Bound Polymer, Amylase (CIW)
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

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