

K843645 SYSTEMATE A AMYLASE HEM 67204Sep 28, 1984
11 days to decisionK843645 · Product code: **CIJ** · Chemistry
Source: <https://www.510kdatabase.net/k843645/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saccharogenic, Amylase (CIJ)
Date received	Sep 17, 1984
Decision date	Sep 28, 1984
Days to decision	11 days
Third-party review	No

APPLICANT

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

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