

**K903332 SYSTEMATE AMYLASE (AMYL) ITEM NUMBER 65404**Aug 17, 1990  
23 days to decisionK903332 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k903332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jul 25, 1990
Decision date	Aug 17, 1990
Days to decision	23 days
Third-party review	No

**APPLICANT**

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

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