

K923677 AMYLASE TESTSep 9, 1992
49 days to decisionK923677 · Product code: **JFJ** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jul 22, 1992
Decision date	Sep 9, 1992
Days to decision	49 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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