

K931582 ETHYLIDENE AMYLAug 19, 1993
141 days to decisionK931582 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k931582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Mar 31, 1993
Decision date	Aug 19, 1993
Days to decision	141 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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