

**K913858 AMYLASE REAGENT (PROCEDURE 577)**Sep 11, 1991  
15 days to decisionK913858 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k913858/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Aug 27, 1991
Decision date	Sep 11, 1991
Days to decision	15 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

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