

**K951548 ACE AMYLASE REAGENT**May 15, 1995  
41 days to decisionK951548 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k951548/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Apr 4, 1995
Decision date	May 15, 1995
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Schiapparelli Biosystems, Inc.</b>
Location	Fairfield, NJ, US
Contact	MARK A SPAIN
510(k) history	24 submissions · 24 cleared · 1993-1999

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