

**K011843 GENZYME DIRECT-AMYLASE TEST REAGENT**Aug 10, 2001  
59 days to decisionK011843 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k011843/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jun 12, 2001
Decision date	Aug 10, 2001
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Corp.</b>
Location	Cambridge, MA, US
Contact	BARBARA PIZZA
Website	<a href="http://www.genzyme.com">http://www.genzyme.com</a>
510(k) history	27 submissions · 27 cleared · 1991-2006

Genzyme Corp. was an American biotechnology company headquartered in Cambridge, Massachusetts. The company specialized in diagnostic and surgical medical devices across multiple therapeutic areas. Genzyme received FDA 510(k) clearances from total submissions between 1991 and 2006. The company's cleared devices spanned chemistry devices, microbiology diagnostics, and surgical implants including wound closure systems and bioresorbable barriers. This regulatory track record reflects the company's broad portfolio across diagnostic and surgical specialties. Genzyme was acquire...

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