

**K993132 GENZYME DIRECT AMYLASE VERIFIER**Oct 4, 1999  
14 days to decisionK993132 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k993132/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Sep 20, 1999
Decision date	Oct 4, 1999
Days to decision	14 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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