

K912519 AMYLASE REAGENTJul 1, 1991
25 days to decisionK912519 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k912519/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jun 6, 1991
Decision date	Jul 1, 1991
Days to decision	25 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Genzyme Corp.
Location	Cambridge, MA, US
Contact	RUSSELL H HERNDON
Website	http://www.genzyme.com
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...
