

K921057 AMYLASE REAGENTMar 27, 1992
22 days to decisionK921057 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k921057/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catalytic Methods, Amylase (JFJ) |
| Date received | Mar 5, 1992 |
| Decision date | Mar 27, 1992 |
| Days to decision | 22 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...
