

K852001 AMY REAGENTJun 10, 1985
34 days to decisionK852001 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k852001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	May 7, 1985
Decision date	Jun 10, 1985
Days to decision	34 days
Third-party review	No

APPLICANT

Company	Alpkem Corp.
Location	Clackamas, OR, US
Contact	YOSIP F WARDA
510(k) history	33 submissions · 33 cleared · 1985-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k852001/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 2, 2026