

K823462 SINGLE VIAL AMYLASE PNP TESTDec 28, 1982
39 days to decisionK823462 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k823462/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Nov 19, 1982
Decision date	Dec 28, 1982
Days to decision	39 days
Third-party review	No

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
510(k) history	340 submissions · 340 cleared · 1976-1999

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k823462/> 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 May 22, 2026