

**K905651 KINETIC AMYLASE DETERMINATION**Jan 31, 1991  
44 days to decisionK905651 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k905651/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Dec 18, 1990
Decision date	Jan 31, 1991
Days to decision	44 days
Third-party review	No

**APPLICANT**

---

Company	<b>Biochemical Trade, Inc.</b>
Location	Miami, FL, US
Contact	ALEJO V ROY
510(k) history	20 submissions · 20 cleared · 1987-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k905651/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026