

**K821869 ULTRAZYME PLUS AMYL**Jul 13, 1982  
18 days to decisionK821869 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k821869/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jun 25, 1982
Decision date	Jul 13, 1982
Days to decision	18 days
Third-party review	No

**APPLICANT**

---

Company	<b>Harleco Diagnostics</b>
Location	Mchenry, IL, US
510(k) history	23 submissions · 23 cleared · 1976-1982

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k821869/> 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 May 14, 2026