

K860665 ALPHA-AMYLASE TESTApr 7, 1986
42 days to decisionK860665 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k860665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Feb 24, 1986
Decision date	Apr 7, 1986
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Sclavo, Inc.
Location	Mchenry, IL, US
Contact	DEBRA HOFMEISTER
510(k) history	82 submissions · 82 cleared · 1977-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k860665/>; 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 June 29, 2026