

K861329 ISOTRAK AMYLASE ISOENZYME CONTROL SETApr 30, 1986
21 days to decisionK861329 · Product code: **JJT** · Chemistry
Source: <https://www.510kdatabase.net/k861329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Controls (assayed And Unassayed) (JJT)
Date received	Apr 9, 1986
Decision date	Apr 30, 1986
Days to decision	21 days
Third-party review	No

APPLICANT

Company	Behring Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	JOHN E HUGHES
510(k) history	145 submissions · 145 cleared · 1976-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k861329/>; 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 28, 2026