

**K853951 ISOTRAK AMYLASE TEST AMYLASE ISOENZYME**Jan 7, 1986  
104 days to decisionK853951 · Product code: **CIJ** · Chemistry  
Source: <https://www.510kdatabase.net/k853951/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saccharogenic, Amylase (CIJ)
Date received	Sep 25, 1985
Decision date	Jan 7, 1986
Days to decision	104 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853951/>, 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 28, 2026