

**K873250 ISOMUNE-AMYLASE AND ISOMUNE-AMYLASE
CONTROL**Oct 20, 1987
64 days to decisionK873250 · Product code: **CIJ** · Chemistry
Source: <https://www.510kdatabase.net/k873250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saccharogenic, Amylase (CIJ)
Date received	Aug 17, 1987
Decision date	Oct 20, 1987
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	ADRIENNE CHOMA
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k873250/> 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 23, 2026