

K913125 ROCHE REAGENT FOR ETHANOLAug 12, 1991
28 days to decisionK913125 · Product code: **DIC** · Chemistry
Source: <https://www.510kdatabase.net/k913125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method (DIC)
Date received	Jul 15, 1991
Decision date	Aug 12, 1991
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913125/> 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