

**K953224 COBAS FP REAGENT APPLICATION FOR FREE
VALPROIC ACID**Oct 30, 1995
139 days to decisionK953224 · Product code: **LEG** · Toxicology
Source: <https://www.510kdatabase.net/k953224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Valproic Acid (LEG)
Date received	Jun 13, 1995
Decision date	Oct 30, 1995
Days to decision	139 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953224/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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