

**K972132 SIGMA DIAGNOSTICS VALPROIC ACID FPIA
REAGENT SET, SIGMA DIAGNOSTICS VALPROIC ACID FPIA
CALIBRATORS**Jul 30, 1997
54 days to decisionK972132 · Product code: **LEG** · Toxicology
Source: <https://www.510kdatabase.net/k972132/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Valproic Acid (LEG)
Date received	Jun 6, 1997
Decision date	Jul 30, 1997
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	WILLIAM R GILBERT
510(k) history	164 submissions · 164 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972132/> 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 May 14, 2026