

K943866 VALPROIC ACID FPIA REAGENT SET AND CALIBRATORSNov 10, 1994
94 days to decisionK943866 · Product code: **LEG** · Chemistry
Source: <https://www.510kdatabase.net/k943866/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Valproic Acid (LEG)
Date received	Aug 8, 1994
Decision date	Nov 10, 1994
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Diagnostics, Inc.
Location	Mchenry, IL, US
Contact	HOYLE D HILL
510(k) history	164 submissions · 164 cleared · 1984-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943866/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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