

**K090358 ARCHITECT IVALPROIC ACID REAGENTS AND
ARCHITECT IVALPROIC ACID CALIBRATORS, MODELS 1P35,
1P35**Aug 6, 2009
175 days to decisionK090358 · Product code: **LEG** · Chemistry
Source: <https://www.510kdatabase.net/k090358/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Valproic Acid (LEG)
Date received	Feb 12, 2009
Decision date	Aug 6, 2009
Days to decision	175 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Laboratories, Inc.
Location	Abbott Park, IL, US
Contact	JUDI WALLACH
510(k) history	6 submissions · 6 cleared · 2002-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090358/> 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 25, 2026