

K042476 VITROS CHEMISTRY PRODUCTS VALP REAGENTDec 1, 2004
79 days to decisionK042476 · Product code: **LEG** · Chemistry
Source: <https://www.510kdatabase.net/k042476/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Valproic Acid (LEG)
Date received	Sep 13, 2004
Decision date	Dec 1, 2004
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary
Other names	VITRO CHEMISTRY PRODUCTS CALIBRATOR KIT 12; VITROS CHEMISTRY PRODUCTS TDM PERFOS

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	CAREY A MAYO
510(k) history	106 submissions · 104 cleared · 1997-2025

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