

K042838 VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 23Dec 9, 2004
56 days to decisionK042838 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k042838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Oct 14, 2004
Decision date	Dec 9, 2004
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary
Other names	VITROS CHEMISTRY PRODUCTS PALB PERFORMANCE VERIFIERS I & II

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042838/> 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 June 28, 2026