

**K123930 VITROS CHEMISTRY PRODUCTS HCY 2 REAGENT,
CALBRATOR KIT 27, HCY 2 PERFORMANCE VERIFIERS I, II
AND III**May 15, 2013
146 days to decisionK123930 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k123930/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Dec 20, 2012
Decision date	May 15, 2013
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123930/> 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 9, 2026