

**K061588 VITROS CHEMISTRY PRODUCTS HCY REAGENT,
VITROS CHEMISTRY PRODUCTS CALIBRATOR KIT 27, HCY
PERFORMANCE VERIFIERS**Jul 21, 2006
43 days to decisionK061588 · Product code: **LPS** · Chemistry
Source: <https://www.510kdatabase.net/k061588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urinary Homocystine (nonquantitative) Test System (LPS)
Date received	Jun 8, 2006
Decision date	Jul 21, 2006
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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