

**K062094 VITROS CHEMISTRY PRODUCTS PCP REAGENT,
CALIBRATOR KIT 26, FS CALIBRATOR 1, DAT PERFORMANCE
VERIFIERS I, II, III, IV, & V**Nov 22, 2006
121 days to decisionK062094 · Product code: **LCM** · Chemistry
Source: <https://www.510kdatabase.net/k062094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Phencyclidine (LCM)
Date received	Jul 24, 2006
Decision date	Nov 22, 2006
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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