

**K062637 VITROS CHEMISTRY PRODUCTS METD REAGENT,
CALBRATOR KIT 26, DAT PERFORMANCE, VERIFIERS I, II, III,
IV & V**Nov 22, 2006
78 days to decisionK062637 · Product code: **DJR** · Chemistry
Source: <https://www.510kdatabase.net/k062637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Methadone (DJR)
Date received	Sep 5, 2006
Decision date	Nov 22, 2006
Days to decision	78 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062637/> 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