

**K062460 VITROS CHEMISTRY PRODUCTS OP REAGENT,  
CALBRATOR KIT 26 AND DAT PERFORMANCE VERIFIERS I, II  
AND III**Dec 15, 2006  
114 days to decisionK062460 · Product code: **DJG** · Chemistry  
Source: <https://www.510kdatabase.net/k062460/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Opiates (DJG)
Date received	Aug 23, 2006
Decision date	Dec 15, 2006
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics, Inc.</b>
Location	Rochester, NY, US
Contact	MARLENE A HANNA
510(k) history	106 submissions · 104 cleared · 1997-2025

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