

**K063164 VITROS CHEMISTRY PRODUCTS THC REAGENT,  
CALIBRATOR KIT 30, FS CALIBRATOR 1, AND DAT  
PERFORMANCE VERIFIERS I, II, III, IV**Dec 28, 2006  
71 days to decisionK063164 · Product code: LDJ · Toxicology  
Source: <https://www.510kdatabase.net/k063164/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Cannabinoids (LDJ)
Date received	Oct 18, 2006
Decision date	Dec 28, 2006
Days to decision	71 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	MICHAEL M BYRNE
510(k) history	106 submissions · 104 cleared · 1997-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k063164/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026