

**K072443 VITROS CHEMISTRY PRODUCTS CA DT SLIDES AND  
DT CALIBRATOR KIT AND VITROS CA ASSAY**Sep 24, 2007  
25 days to decisionK072443 · Product code: **CJY** · Chemistry  
Source: <https://www.510kdatabase.net/k072443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Azo Dye, Calcium (CJY)
Date received	Aug 30, 2007
Decision date	Sep 24, 2007
Days to decision	25 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 HANNA
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/k072443/> 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 26, 2026