

**K001679 VITROS CHEMISTRY PRODUCTS AST SLIDE AND CHEMISTRY PRODUCTS CALIBRATOR KIT 3**Jun 28, 2000  
27 days to decisionK001679 · Product code: **CIT** · Chemistry  
Source: <https://www.510kdatabase.net/k001679/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Nadh Oxidation/nad Reduction, Ast/sgot (CIT)
Date received	Jun 1, 2000
Decision date	Jun 28, 2000
Days to decision	27 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 SHULMAN
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/k001679/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026