

**K983690 VITROS IMMUNODIAGNOSTIC PRODUCTS CA 15-3  
CALBRATORS,VITROS IMMUNODIAGNOSTIC PRODUCTS CA  
15-3 REAGENT PACK**Feb 2, 1999  
104 days to decisionK983690 · Product code: **MOI** · Immunology  
Source: <https://www.510kdatabase.net/k983690/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Oct 21, 1998
Decision date	Feb 2, 1999
Days to decision	104 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	ANNE ZAVERTNIK
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/k983690/> 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