

**K983674 VITROS IMMUNODIAGNOSTIC PRODUCTS: NTX  
CALBRATORS, NTX REAGENT PACK, NTX CONTROLS**Jan 29, 1999  
101 days to decisionK983674 · Product code: **JMM** · Chemistry  
Source: <https://www.510kdatabase.net/k983674/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Column Chromatography & Color Development, Hydroxyproline (JMM)
Date received	Oct 20, 1998
Decision date	Jan 29, 1999
Days to decision	101 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/k983674/>; 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