

**K984166 VITROS IMMUNODIAGNOSTIC PRODUCTS FOLATE REAGENT PACK 1/2, VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12/FOLATE REAGENT P3**Feb 5, 1999  
77 days to decisionK984166 · Product code: **CGN** · Chemistry  
Source: <https://www.510kdatabase.net/k984166/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Nov 20, 1998
Decision date	Feb 5, 1999
Days to decision	77 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/k984166/>; 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