

**K984321 VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12, REAGENT PACK 1/2, FOLATE REAGENT PACK 3, ANF CALIBRATORS**

Jan 22, 1999  
50 days to decision

K984321 · Product code: **CDD** · Immunology  
Source: <https://www.510kdatabase.net/k984321/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Dec 3, 1998
Decision date	Jan 22, 1999
Days to decision	50 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/k984321/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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