

**K990026 VITROS IMMUNODIAGNOSTIC PRODUCTS FOLATE
VERIFIERS, VITROS IMMUNODIAGNOSTIC PRODUCTS
VITAMIN B12 RANGE VERIFIERS**Jan 29, 1999
24 days to decisionK990026 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k990026/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 5, 1999
Decision date	Jan 29, 1999
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	ANNE ZAVERTNIK
510(k) history	106 submissions · 104 cleared · 1997-2025

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