

K001266 VITROS IMMUNODIAGNOSTIC PRODUCTS FOLATE REAGENT PACK 1/2, VITAMIN B12/FOLATE REAGENT PACK 3, PRODUCTS RED CELL FOLATE PAMay 2, 2000
12 days to decisionK001266 · Product code: **CGN** · Chemistry
Source: <https://www.510kdatabase.net/k001266/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	Apr 20, 2000
Decision date	May 2, 2000
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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