

K013899 VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12, REAGENT PACK 1/2, FOLATE REAGENT PACK 3, CALIBRATORSJan 24, 2002
62 days to decisionK013899 · Product code: **CDD** · Toxicology
Source: <https://www.510kdatabase.net/k013899/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioassay, Vitamin B12 (CDD)
Date received	Nov 23, 2001
Decision date	Jan 24, 2002
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	MARLENE A SHULMAN
510(k) history	38 submissions · 38 cleared · 1999-2024

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immunochemistry. Now part of QuidelOrtho, the brand operates with global research and development centered in Rochester, New York. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions since 1999. Recent clearances span chemistry devices, immunology assays, and microbiology reagents, reflecting the company's focus on diagnostic platforms and assays for disease detection and blood compatibility testing. The V...