

**K013900 VITROS IMMUNODIAGNOSTIC PRODUCTS VITAMIN B12 RANGE VERIFIERS**Dec 21, 2001  
28 days to decisionK013900 · Product code: **JJX** · Toxicology  
Source: <https://www.510kdatabase.net/k013900/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Nov 23, 2001
Decision date	Dec 21, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho-Clinical Diagnostics</b>
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...

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Device record: <https://www.510kdatabase.net/k013900/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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