

**K022901 VITROS IMMUNODIAGNOSTIC PRODUCTS
PROGESTERONE REAGENT PACK AND CALIBRATORS**Sep 27, 2002
24 days to decisionK022901 · Product code: **JIS** · Chemistry
Source: <https://www.510kdatabase.net/k022901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Primary (JIS)
Date received	Sep 3, 2002
Decision date	Sep 27, 2002
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	MARLENE HANNA
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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