

**K032296 VITROS IMMUNODIAGNOSTIC PRODUCTS
PROGESTRONE REAGENT PACK AND CALIBRATORS**Aug 13, 2003
19 days to decisionK032296 · Product code: **JIS** · Chemistry
Source: <https://www.510kdatabase.net/k032296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Primary (JIS)
Date received	Jul 25, 2003
Decision date	Aug 13, 2003
Days to decision	19 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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