

K003112 VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBS CONTROLSNov 2, 2000
29 days to decisionK003112 · Product code: **JJX** · Microbiology
Source: <https://www.510kdatabase.net/k003112/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Oct 4, 2000
Decision date	Nov 2, 2000
Days to decision	29 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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