

K011250 VITROS IMMUNODIAGNOSTIC PRODUCTS HBSAG CONTROLSJun 13, 2001
50 days to decisionK011250 · Product code: **JJX** · Microbiology
Source: <https://www.510kdatabase.net/k011250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Apr 24, 2001
Decision date	Jun 13, 2001
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011250/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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