

**K032993 VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC
IGM CONTROLS**Oct 31, 2003
36 days to decisionK032993 · Product code: **JJX** · Microbiology
Source: <https://www.510kdatabase.net/k032993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 25, 2003
Decision date	Oct 31, 2003
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032993/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026