

K042303 VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBS CONTROLSSep 27, 2004
33 days to decisionK042303 · Product code: **JJX** · Microbiology
Source: <https://www.510kdatabase.net/k042303/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Aug 25, 2004
Decision date	Sep 27, 2004
Days to decision	33 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	SARAH GLOVER
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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Device record: <https://www.510kdatabase.net/k042303/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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