

K033127 VITROS IMMUNODIAGNOSTIC PRODUCTS ANTI-HBC CONTROLSOct 31, 2003
31 days to decisionK033127 · Product code: **JJX** · Microbiology
Source: <https://www.510kdatabase.net/k033127/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 30, 2003
Decision date	Oct 31, 2003
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics
Location	Rochester, NY, US
Contact	SARAH PARSONS
510(k) history	38 submissions · 38 cleared · 1999-2024

Ortho-Clinical Diagnostics is an in vitro diagnostics company specializing in clinical laboratory testing and immuno-hematology. 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/k033127/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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