

**K990061 VITROS IMMUNODIAGNOSTIC PRODUCTS AFP
RANGE VERIFIERS**Jan 25, 1999
17 days to decisionK990061 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k990061/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 8, 1999
Decision date	Jan 25, 1999
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990061/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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