

**K990783 VITROS IMMUNODIAGNOSTIC PRODUCTS CA15-3
RANGE VERIFIERS, CA125 II RANGE VERIFIERS, PSA RANGE
VERIFIERS**Mar 25, 1999
16 days to decisionK990783 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k990783/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Mar 9, 1999
Decision date	Mar 25, 1999
Days to decision	16 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

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