

K990984 VITROS IMMUNODIAGNOSTIC PRODUCTS CEA RANGE VERIFIERSApr 8, 1999
15 days to decisionK990984 · Product code: **JJX** · Immunology
Source: <https://www.510kdatabase.net/k990984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Mar 24, 1999
Decision date	Apr 8, 1999
Days to decision	15 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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