

K990016 VITROS IMMUNODIAGNOSTIC PRODUCTS ANEMIA CONTROLSMay 19, 1999
135 days to decisionK990016 · Product code: **JJY** · Immunology
Source: <https://www.510kdatabase.net/k990016/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jan 4, 1999
Decision date	May 19, 1999
Days to decision	135 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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