

**K984011 VITROS IMMUNODIAGNOSTIC PRODUCTS CORTISOL  
RANGE VERIFIERS**Dec 7, 1998  
27 days to decisionK984011 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k984011/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Nov 10, 1998
Decision date	Dec 7, 1998
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k984011/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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