

**K983507 VITROS IMMUNODIAGNOSTIC PRODUCTS  
TESTOSTERONE ASSAY**

Nov 4, 1998  
28 days to decision

K983507 · Product code: JJY · Chemistry  
Source: <https://www.510kdatabase.net/k983507/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 7, 1998
Decision date	Nov 4, 1998
Days to decision	28 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/k983507/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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