

**K984289 VITROS IMMUNODIAGNOSTIC PRODUCTS PSA  
CALIBRATORS, VITROS IMMUNODIAGNOSTIC PRODUCTS  
PSA REAGENT PACK**Mar 12, 1999  
101 days to decisionK984289 · Product code: **LTJ** · Immunology  
Source: <https://www.510kdatabase.net/k984289/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Dec 1, 1998
Decision date	Mar 12, 1999
Days to decision	101 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/k984289/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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