

**K983031 VITROS IMMUNODIAGNOSTIC PRODUCTS AFP
ASSAY**Dec 18, 1998
109 days to decisionK983031 · Product code: **LOJ** · Immunology
Source: <https://www.510kdatabase.net/k983031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ)
Date received	Aug 31, 1998
Decision date	Dec 18, 1998
Days to decision	109 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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