

**K983875 VITROS IMMUNODIAGNOSTIC PRODUCTS CA 125 II
CALIBRATORS, VITROS IMMUNODIAGNOSTIC PRODUCTS CA
125 II REAGENT PACK**May 14, 1999
193 days to decisionK983875 · Product code: LTK · Immunology
Source: <https://www.510kdatabase.net/k983875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Nov 2, 1998
Decision date	May 14, 1999
Days to decision	193 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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