

**K990943 VITROS IMMUNODIAGNOSTIC PRODUCTS CEA
CALIBRATORS, VITROS IMMUNODIAGNOSTIC PRODUCTS
CEA REAGENT PACK**Jun 1, 1999
71 days to decisionK990943 · Product code: **DHX** · Immunology
Source: <https://www.510kdatabase.net/k990943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	Mar 22, 1999
Decision date	Jun 1, 1999
Days to decision	71 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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