

**K041322 VITROS IMMUNODIAGNOSTIC PRODUCTS CEA
REAGENT PACK/CALIBRATOR/RANGE VERIFIERS**Jun 17, 2004
30 days to decisionK041322 · Product code: **DHX** · Immunology
Source: <https://www.510kdatabase.net/k041322/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Carcinoembryonic Antigen (DHX)
Date received	May 18, 2004
Decision date	Jun 17, 2004
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ortho-Clinical Diagnostics, Inc.
Location	Rochester, NY, US
Contact	SARAH PARSONS
510(k) history	106 submissions · 104 cleared · 1997-2025

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