

**K042643 VITROS CHEMISTRY PRODUCT MALB REAGENT,
CALBRATOR KIT 24, MALB PERFORMANCE VERIFIERS I AND
II**Nov 18, 2004
52 days to decisionK042643 · Product code: **DCF** · Chemistry
Source: <https://www.510kdatabase.net/k042643/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Albumin, Antigen, Antiserum, Control (DCF)
Date received	Sep 27, 2004
Decision date	Nov 18, 2004
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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