

K042521 VITROS CHEMISTRY PRODUCTS APOA1 AND APOB REAGENTS, CALIBRATOR KITS 21 AND 22 AND APOA1 AND APOB PERFORMANCE VERIFIERSNov 18, 2004
63 days to decisionK042521 · Product code: **JIT** · Chemistry
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
Date received	Sep 16, 2004
Decision date	Nov 18, 2004
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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