

**K041720 VITROS CHEMISTRY PRODUCTS DLDL REAGENT,
CALBRATOR KIT 19, FS CALBRATOR 1 AND PERFORMANCE
VERIFIERS I AND II**Aug 25, 2004
62 days to decisionK041720 · Product code: **MRR** · Chemistry
Source: <https://www.510kdatabase.net/k041720/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Low Density, Lipoprotein (MRR)
Date received	Jun 24, 2004
Decision date	Aug 25, 2004
Days to decision	62 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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