

K120609 VITROS CHEMISTRY PRODUCTS DHDL SLIDESSep 7, 2012
191 days to decisionK120609 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k120609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Feb 29, 2012
Decision date	Sep 7, 2012
Days to decision	191 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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