

**K012593 VITROS CHEMISTRY PRODUCTS MAGNETIC HDL-
CHOLESTEROL REAGENT, VITROS CHEMISTRY PRODUCTS
CALIBRATOR KIT 2**Aug 30, 2001
20 days to decisionK012593 · Product code: **LBR** · Chemistry
Source: <https://www.510kdatabase.net/k012593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ldl & Vldl Precipitation, Hdl (LBR)
Date received	Aug 10, 2001
Decision date	Aug 30, 2001
Days to decision	20 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012593/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026