

K943028 HDL QVETDec 7, 1994
163 days to decisionK943028 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k943028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Jun 27, 1994
Decision date	Dec 7, 1994
Days to decision	163 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Prisma Systems
Location	Rome, NY, US
Contact	LARRY BEASLEY
510(k) history	27 submissions · 27 cleared · 1994-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943028/> 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 29, 2026