

K973988 RDI HOMOGENEOUS HDL CHOLESTEROL TESTDec 22, 1997
62 days to decisionK973988 · Product code: **LBS** · Chemistry
Source: <https://www.510kdatabase.net/k973988/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ldl & Vldl Precipitation, Cholesterol Via Esterase-oxidase, Hdl (LBS)
Date received	Oct 21, 1997
Decision date	Dec 22, 1997
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Reference Diagnostics, Inc.
Location	Arlington, MA, US
Contact	JOSEPH LAWLOR
510(k) history	17 submissions · 17 cleared · 1990-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973988/> 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