

K944975 MAGNETIC HDL CHOLESTEROL TESTAug 2, 1995
295 days to decisionK944975 · Product code: **LBR** · Chemistry
Source: <https://www.510kdatabase.net/k944975/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ldl & Vldl Precipitation, Hdl (LBR) |
| Date received | Oct 11, 1994 |
| Decision date | Aug 2, 1995 |
| Days to decision | 295 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/k944975/> 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