

K893966 HDL PRECIPITATING REAGENTJul 25, 1989
53 days to decisionK893966 · Product code: **LBR** · Chemistry
Source: <https://www.510kdatabase.net/k893966/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ldl & Vldl Precipitation, Hdl (LBR) |
| Date received | Jun 2, 1989 |
| Decision date | Jul 25, 1989 |
| Days to decision | 53 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Systems |
| Location | Mchenry, IL, US |
| Contact | ANNA G BENTLEY |
| 510(k) history | 14 submissions · 14 cleared · 1983-1991 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k893966/>; 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