

**K881244 HDL CHOLESTEROL KIT**Jun 10, 1988  
79 days to decisionK881244 · Product code: **LBR** · Chemistry  
Source: <https://www.510kdatabase.net/k881244/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Ldl & Vldl Precipitation, Hdl (LBR) |
| Date received         | Mar 23, 1988                        |
| Decision date         | Jun 10, 1988                        |
| Days to decision      | 79 days                             |
| Third-party review    | No                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Trace Scientific , Ltd.</b>          |
| Location       | Clayton, Vic 3168, AU                   |
| Contact        | P. J RUTHVEN                            |
| 510(k) history | 55 submissions · 55 cleared · 1986-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k881244/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026