

**K915870 OPUS RUBELLA TEST SYSTEM**Mar 23, 1992  
83 days to decisionK915870 · Product code: **LFX** · Pathology  
Source: <https://www.510kdatabase.net/k915870/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                 |
| Submission type       | Traditional  |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Rubella (LFX) |
| Date received         | Dec 31, 1991                                       |
| Decision date         | Mar 23, 1992                                       |
| Days to decision      | 83 days  |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Pb Diagnostics, Inc.</b>           |
| Location       | Westwood, MA, US                      |
| Contact        | KATHLEEN DRAY-LYONS                   |
| 510(k) history | 4 submissions · 4 cleared · 1991-1993 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k915870/> 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 May 14, 2026