

**K042731 ARCHITECT CA 125 II ASSAY**Nov 19, 2004  
49 days to decisionK042731 · Product code: LTK · Immunology  
Source: <https://www.510kdatabase.net/k042731/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Traditional   |
| Device classification | Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK) |
| Date received         | Oct 1, 2004   |
| Decision date         | Nov 19, 2004  |
| Days to decision      | 49 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Fujirebio Diagnostics, Inc.</b>      |
| Location       | North Caldwell, NJ, US                  |
| Contact        | KIMBERLY PETERSON                       |
| 510(k) history | 45 submissions · 43 cleared · 1989-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042731/> 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 28, 2026