

**K142895 LUMIPULSE G1200 System, LUMIPULSE G CA 125II  
Immunoreaction Cartridges, LUMIPULSE G CA 125II Calibrators**

May 21, 2015  
230 days to decision

K142895 · Product code: LTK · Immunology  
Source: <https://www.510kdatabase.net/k142895/>

**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 3, 2014
Decision date	May 21, 2015
Days to decision	230 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	Diana Dickson
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/k142895/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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