

**K890091 MODIFIED LABSYSTEMS&apos; RUBELLA IGG EIA  
TEST KIT**Feb 3, 1989  
29 days to decisionK890091 · Product code: LFX · Microbiology  
Source: <https://www.510kdatabase.net/k890091/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jan 5, 1989
Decision date	Feb 3, 1989
Days to decision	29 days
Third-party review	No

**APPLICANT**

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Company	<b>Labsystems, Inc.</b>
Location	Walker, MI, US
Contact	PAIVI SORMUNEN
510(k) history	17 submissions · 17 cleared · 1984-1993

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k890091/>; 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