

**K885082 IMMUNODOT RUBELLA TEST**Feb 2, 1989  
55 days to decisionK885082 · Product code: **LFX** · Microbiology  
Source: <https://www.510kdatabase.net/k885082/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Dec 9, 1988
Decision date	Feb 2, 1989
Days to decision	55 days
Third-party review	No

**APPLICANT**

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Company	<b>General Biometrics, Inc.</b>
Location	San Diego, CA, US
Contact	E. F WADDELL
510(k) history	23 submissions · 23 cleared · 1989-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k885082/>; 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 30, 2026