

**K914420 ELISA RUBELLA IGM**Dec 27, 1991  
85 days to decisionK914420 · Product code: **LFX** · Microbiology  
Source: <https://www.510kdatabase.net/k914420/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Oct 3, 1991
Decision date	Dec 27, 1991
Days to decision	85 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sclavo, Inc.</b>
Location	Mchenry, IL, US
Contact	MARTIN KING
510(k) history	82 submissions · 82 cleared · 1977-1992

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k914420/> 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