

**K841200 RUBELLA IGG ANTIBODY ELISA TEST SYS**May 21, 1984  
61 days to decisionK841200 · Product code: **LFX** · Microbiology  
Source: <https://www.510kdatabase.net/k841200/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Mar 21, 1984
Decision date	May 21, 1984
Days to decision	61 days
Third-party review	No

**APPLICANT**

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Company	<b>Ortho Diagnostic Systems, Inc.</b>
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997

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Device record: <https://www.510kdatabase.net/k841200/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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