

**K921573 RUBELLA IGM**Aug 27, 1992  
147 days to decisionK921573 · Product code: **LFX** · Microbiology  
Source: <https://www.510kdatabase.net/k921573/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Apr 2, 1992
Decision date	Aug 27, 1992
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Clark Laboratories, Inc.</b>
Location	Blairstown, NJ, US
Contact	Gary Lehnus
510(k) history	14 submissions · 14 cleared · 1992-1998

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