

**K122397 LIAISON RUBELLA IGM, LIAISON CONTROL  
RUBELLA IGM**Sep 6, 2012  
30 days to decisionK122397 · Product code: LFX · Microbiology  
Source: <https://www.510kdatabase.net/k122397/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Aug 7, 2012
Decision date	Sep 6, 2012
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>DiaSorin, Inc.</b>
Location	Ellicott City, MD, US
Contact	CAROL A DEPOUW
510(k) history	71 submissions · 70 cleared · 1998-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122397/>; 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 13, 2026