

**K072617 ELECSYS RUBELLA IGG IMMUNOASSAY**Dec 5, 2008  
445 days to decisionK072617 · Product code: **LFX** · Microbiology  
Source: <https://www.510kdatabase.net/k072617/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Sep 17, 2007
Decision date	Dec 5, 2008
Days to decision	445 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics Corp.</b>
Location	Indianapolis, IN, US
Contact	THERESA A BUSH
510(k) history	264 submissions · 263 cleared · 1999-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072617/> 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 9, 2026