

**K963613 IMMULITE RUBELLA IGG**Apr 2, 1997  
204 days to decisionK963613 · Product code: **LFX** · Microbiology  
Source: <https://www.510kdatabase.net/k963613/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Sep 10, 1996
Decision date	Apr 2, 1997
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diagnostic Products Corp.</b>
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE
510(k) history	321 submissions · 321 cleared · 1976-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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