

**K012077 IMMULITE RUBELLA IGM,LKRM1, LKRM2, IMMULITE
2000 RUBELLA IGM, MODEL L2KRM2, L2KRM6**Jan 10, 2002
192 days to decisionK012077 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k012077/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jul 2, 2001
Decision date	Jan 10, 2002
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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