

K080766 VIDAS RUB IGGDec 23, 2008
280 days to decisionK080766 · Product code: **LFX** · Microbiology
Source: <https://www.510kdatabase.net/k080766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Mar 18, 2008
Decision date	Dec 23, 2008
Days to decision	280 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	bioMerieux, Inc.
Location	Mchenry, IL, US
Contact	NIKITA S MAPP
510(k) history	251 submissions · 250 cleared · 1983-2026

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