

K853696 RUBELLA IGG EIA TEST KITJun 17, 1986
285 days to decisionK853696 · Product code: **LFX** · Microbiology
Source: <https://www.510kdatabase.net/k853696/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Sep 5, 1985
Decision date	Jun 17, 1986
Days to decision	285 days
Third-party review	No

APPLICANT

Company	Labsystems, Inc.
Location	Walker, MI, US
Contact	NANCY SKOWRONSKI
510(k) history	17 submissions · 17 cleared · 1984-1993

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