

K862431 RUBELLA IGM EIA TEST KITAug 8, 1986
43 days to decisionK862431 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k862431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jun 26, 1986
Decision date	Aug 8, 1986
Days to decision	43 days
Third-party review	No

APPLICANT

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

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