

K905079 ORTHO RUBELLA-M ANTIBODY ELISA TESTDec 4, 1990
21 days to decisionK905079 · Product code: **LFX** · Microbiology
Source: <https://www.510kdatabase.net/k905079/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Nov 13, 1990
Decision date	Dec 4, 1990
Days to decision	21 days
Third-party review	No

APPLICANT

Company	Ortho Diagnostic Systems, Inc.
Location	Carpinteria, CA, US
Contact	KIM W GRAY
510(k) history	126 submissions · 126 cleared · 1981-1997

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