

K822342 ORTHO RUBELLA ELISA TEST SYSTEMMar 17, 1983
225 days to decisionK822342 · Product code: **LFX** · Microbiology
Source: <https://www.510kdatabase.net/k822342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Aug 4, 1982
Decision date	Mar 17, 1983
Days to decision	225 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k822342/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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