

**K884617 ORTHO RESULT PLUS/RUBELLA RAPID COLOR.
IMMUNOASSAY**Feb 2, 1989
90 days to decisionK884617 · Product code: LFX · Microbiology
Source: <https://www.510kdatabase.net/k884617/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Nov 4, 1988
Decision date	Feb 2, 1989
Days to decision	90 days
Third-party review	No

APPLICANT

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

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