FDA 510(k) Premarket Notification

K822342 ORTHO RUBELLA ELISA TEST SYSTEM

CLEARED

Mar 17, 1983
225 days to decision

K822342 · 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