FDA 510(k) Premarket Notification

K896479 ORTHO* RUBELLA-G ANTIBODY ELISA TEST

CLEARED

Dec 29, 1989
46 days to decision

K896479 · Product code: **LFX** · Microbiology
Source: https://www.510kdatabase.net/k896479/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Nov 13, 1989
Decision date	Dec 29, 1989
Days to decision	46 days
Third-party review	No

APPLICANT

Company	**Ortho Diagnostic Systems, Inc.**
Location	Carpinteria, CA, US
Contact	LARRY D MCCLAIN,PHD
510(k) history	126 submissions · 126 cleared · 1981-1997