

**K896479 ORTHO\* RUBELLA-G ANTIBODY ELISA TEST**Dec 29, 1989  
46 days to decisionK896479 · Product code: LFX · Microbiology  
Source: <https://www.510kdatabase.net/k896479/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k896479/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026