

K883938 ORTHO* SYPHILIS-M ANTIBODY ELISA TESTDec 22, 1988
94 days to decisionK883938 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k883938/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Sep 19, 1988
Decision date	Dec 22, 1988
Days to decision	94 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

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