

K091361 IMMULITE 2000 SYPHILIS SCREEN TEST SYSTEMDec 16, 2009
222 days to decisionK091361 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k091361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	May 8, 2009
Decision date	Dec 16, 2009
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Healthcare Diagnostics
Location	Newark, DE, US
Contact	CAROLYN K GEORGE
510(k) history	92 submissions · 92 cleared · 2008-2025

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