

K050590 ENZY-WELL SYPHILIS IGG, MODEL 91106Aug 10, 2006
520 days to decisionK050590 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k050590/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Mar 8, 2005
Decision date	Aug 10, 2006
Days to decision	520 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Diesse Diagnostica Senese S.P.A.
Location	Miami, FL, US
Contact	GLORIA SCHLANSER
510(k) history	2 submissions · 2 cleared · 2006-2007

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