

K061247 DIASORIN LIAISON TREPONEMA ASSAYJul 31, 2006
89 days to decisionK061247 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k061247/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	May 3, 2006
Decision date	Jul 31, 2006
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DiaSorin, Inc.
Location	Ellicott City, MD, US
Contact	CAROL A DEPOUW
510(k) history	71 submissions · 70 cleared · 1998-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061247/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026