

K911627 IMMUNODOT BORRELIA (LYME) TESTApr 8, 1992
363 days to decisionK911627 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k911627/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Apr 11, 1991
Decision date	Apr 8, 1992
Days to decision	363 days
Third-party review	No

APPLICANT

Company	General Biometrics, Inc.
Location	San Diego, CA, US
Contact	BRYAN L KIEHL
510(k) history	23 submissions · 23 cleared · 1989-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911627/>; 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 30, 2026