

**K911590 IMMUNOWELL BORRELIA (LYME)TEST**Dec 20, 1991  
255 days to decisionK911590 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k911590/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Apr 9, 1991
Decision date	Dec 20, 1991
Days to decision	255 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911590/>, Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026