

K911599 IMMUNOWELL LYME (P39 RECOMBINANT) TESTDec 30, 1991
265 days to decisionK911599 · Product code: **LSR** · Microbiology
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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 30, 1991
Days to decision	265 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

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