

K894410 IMMUNODOT LYME TESTOct 30, 1989
105 days to decisionK894410 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k894410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jul 17, 1989
Decision date	Oct 30, 1989
Days to decision	105 days
Third-party review	No

APPLICANT

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

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