

K953683 MMUNO DOT BORRELIA DOT BLOT M TESTMay 3, 1996
270 days to decisionK953683 · Product code: **LSR** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Aug 7, 1995
Decision date	May 3, 1996
Days to decision	270 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Genbio
Location	San Diego, CA, US
Contact	Bryan Kiehl
510(k) history	10 submissions · 10 cleared · 1996-2001

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