

K951709 MARDX LYME DISEASE (IGM) MARBLOT STRIP TEST SYSTEMJun 7, 1996
421 days to decisionK951709 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k951709/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Apr 13, 1995
Decision date	Jun 7, 1996
Days to decision	421 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mardx Diagnostics, Inc.
Location	Scotch Plains, NJ, US
Contact	ARTHUR MARKOVITS
510(k) history	8 submissions · 8 cleared · 1989-1997

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