

K950829 MARDX LYME DISEASE (IGG) MARBLOT STRIP TEST SYSTEM

Jun 5, 1996
468 days to decision

K950829 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k950829/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Feb 23, 1995
Decision date	Jun 5, 1996
Days to decision	468 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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Device record: <https://www.510kdatabase.net/k950829/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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