

K894293 MARDX LYME DISEASE EIA (IGM) TEST SYSTEMAug 21, 1989
59 days to decisionK894293 · Product code: **LSR** · Microbiology
Source: <https://www.510kdatabase.net/k894293/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jun 23, 1989
Decision date	Aug 21, 1989
Days to decision	59 days
Third-party review	No

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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