

**K894609 MARDX LYME DISEASE IFA (IGM) TEST SYSTEM**Sep 19, 1989  
61 days to decisionK894609 · Product code: **LSR** · Microbiology  
Source: <https://www.510kdatabase.net/k894609/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagent, Borrelia Serological Reagent (LSR)
Date received	Jul 20, 1989
Decision date	Sep 19, 1989
Days to decision	61 days
Third-party review	No

**APPLICANT**

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Company	<b>Mardx, Inc.</b>
Location	Scotch Plains, NJ, US
Contact	ARTHUR MARKOVITS
510(k) history	1 submissions · 1 cleared · 1989-1989

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