

K960182 DSDNA IMMUNOGLOBULIN EIA TEST SYSTEMMar 20, 1996
64 days to decisionK960182 · Product code: **LRM** · Immunology
Source: <https://www.510kdatabase.net/k960182/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Jan 16, 1996
Decision date	Mar 20, 1996
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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