

**K964787 MARDX ENA IGG IMMUNOSTRIPE TEST SYSTEM /
MARDX ENA IGG MARSTRIPE TEST SYSTEM**Apr 8, 1997
130 days to decisionK964787 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k964787/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Nov 29, 1996
Decision date	Apr 8, 1997
Days to decision	130 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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