

K950110 MARDX MITOCHONDRIA EIA TEST SYSTEMMay 15, 1995
124 days to decisionK950110 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k950110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jan 11, 1995
Decision date	May 15, 1995
Days to decision	124 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hogan & Hartson
Location	Mchenry, IL, US
Contact	PATRICIA B SHRADER
510(k) history	26 submissions · 25 cleared · 1980-1998

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