

K946218 MARDX ENA EIA TEST SYSTEMMay 15, 1995
145 days to decisionK946218 · Product code: **LJM** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Dec 21, 1994
Decision date	May 15, 1995
Days to decision	145 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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