

K852840 ENZYME ANTINUCLEAR ANTIBODY SCREENING TESTAug 1, 1985
27 days to decisionK852840 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k852840/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jul 5, 1985
Decision date	Aug 1, 1985
Days to decision	27 days
Third-party review	No

APPLICANT

Company	Modern Diagnostics, Inc.
Location	Sacramento, CA, US
Contact	VIRGINIA J LIPP
510(k) history	5 submissions · 5 cleared · 1985-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k852840/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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