

K852231 ANA/LITE-HEP-2 TEST SYSTEMJul 10, 1985
49 days to decisionK852231 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k852231/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	May 22, 1985
Decision date	Jul 10, 1985
Days to decision	49 days
Third-party review	No

APPLICANT

Company	Immuno-Products Industries
Location	Mchenry, IL, US
Contact	HOWARD RUBINSTEIN
510(k) history	12 submissions · 12 cleared · 1981-1985

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k852231/>, Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026