

K874195 LA ANTIBODY TEST KITMar 11, 1988
149 days to decisionK874195 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k874195/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Oct 14, 1987
Decision date	Mar 11, 1988
Days to decision	149 days
Third-party review	No

APPLICANT

Company	Lipogen, Inc.
Location	Knoxville, TN, US
Contact	MICHAEL W FOUNTAIN
510(k) history	15 submissions · 15 cleared · 1987-1990

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k874195/>; 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