

K875246 LIPOGEN ANA TEST KITFeb 10, 1988
50 days to decisionK875246 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k875246/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Dec 22, 1987
Decision date	Feb 10, 1988
Days to decision	50 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k875246/>; 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