

K896347 IMMUNODOT AUTOIMMUNE SCREENING PANEL 1Dec 5, 1989
32 days to decisionK896347 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k896347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Nov 3, 1989
Decision date	Dec 5, 1989
Days to decision	32 days
Third-party review	No

APPLICANT

Company	General Biometrics, Inc.
Location	San Diego, CA, US
Contact	KIEHL, PHD
510(k) history	23 submissions · 23 cleared · 1989-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k896347/>; 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