

K980810 SERAQUEST ANTI-SSAMay 12, 1998
70 days to decisionK980810 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k980810/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Mar 3, 1998
Decision date	May 12, 1998
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Quest Intl., Inc.
Location	Fort Smith, AR, US
Contact	ROBERT A CORT
510(k) history	25 submissions · 25 cleared · 1989-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980810/> 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 23, 2026