

**K895995 RHEUMELISA ASSAY FOR SS-B/LA
AUTOANTIBODIES**Oct 27, 1989
14 days to decisionK895995 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k895995/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Oct 13, 1989
Decision date	Oct 27, 1989
Days to decision	14 days
Third-party review	No

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895995/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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