

**K895997 RHEUMELISA ASSAY FOR RNP AUTOANTIBODIES**Nov 6, 1989  
24 days to decisionK895997 · Product code: **LKO** · Immunology  
Source: <https://www.510kdatabase.net/k895997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-rnp Antibody, Antigen And Control (LKO)
Date received	Oct 13, 1989
Decision date	Nov 6, 1989
Days to decision	24 days
Third-party review	No

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k895997/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026