

**K892421 MODIFIED ACCESS R-CLONE ANA/RF SCREENING TEST**May 9, 1989  
29 days to decisionK892421 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k892421/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Apr 10, 1989
Decision date	May 9, 1989
Days to decision	29 days
Third-party review	No

**APPLICANT**

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Company	<b>Lipogen, Inc.</b>
Location	Knoxville, TN, US
Contact	DEES PH.D.
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/k892421/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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