

**K940641 ELIAS ANA TOTAL**Mar 25, 1994  
39 days to decisionK940641 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k940641/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Feb 14, 1994
Decision date	Mar 25, 1994
Days to decision	39 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Elias U.S.A., Inc.</b>
Location	Osceola, WI, US
Contact	GOTTFRIED KELLERMANN
510(k) history	54 submissions · 54 cleared · 1992-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k940641/> 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 29, 2026