

**K951186 VARELISA ANA-4 SCREEN**Apr 17, 1995  
32 days to decisionK951186 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k951186/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Mar 16, 1995
Decision date	Apr 17, 1995
Days to decision	32 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
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/k951186/>; 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