

**K951205 VARELISA ANA PROFILE**Apr 17, 1995  
31 days to decisionK951205 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k951205/>**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 17, 1995
Decision date	Apr 17, 1995
Days to decision	31 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	GITTFRIED KELLERMAN
510(k) history	54 submissions · 54 cleared · 1992-1997

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