

**K963291 VARELISA ANA (4) PROFILE**Sep 30, 1996  
40 days to decisionK963291 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k963291/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Aug 21, 1996
Decision date	Sep 30, 1996
Days to decision	40 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, PH.D.
510(k) history	54 submissions · 54 cleared · 1992-1997

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