

K944171 VARELISA CENTROMERE ANTIBODIESDec 22, 1994
118 days to decisionK944171 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k944171/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Aug 26, 1994
Decision date	Dec 22, 1994
Days to decision	118 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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