

K944334 VARELISA COMBINED DNA ANTIBODIES EIAApr 17, 1995
223 days to decisionK944334 · Product code: **LRM** · Immunology
Source: <https://www.510kdatabase.net/k944334/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Sep 6, 1994
Decision date	Apr 17, 1995
Days to decision	223 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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