

K950031 VARELISA DSDNA ANTIBODIES (FARR VERSION)Mar 10, 1995
65 days to decisionK950031 · Product code: **LRM** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Jan 4, 1995
Decision date	Mar 10, 1995
Days to decision	65 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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