

K953586 VARELISA PR3-ANCAJan 26, 1996
178 days to decisionK953586 · Product code: **MOB** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Aug 1, 1995
Decision date	Jan 26, 1996
Days to decision	178 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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