

K953587 VARELISA MPO-ANCAJan 26, 1996
178 days to decisionK953587 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k953587/>**SUBMISSION DETAILS**

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 KELLERMANN
510(k) history	54 submissions · 54 cleared · 1992-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953587/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026