

K981750 WIELISA ANTI-GBM, ANCA SCREENING KIT TEST SYSTEMJul 22, 1998
65 days to decisionK981750 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k981750/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	May 18, 1998
Decision date	Jul 22, 1998
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wieslab AB
Location	Frederick, MD, US
Contact	WILLIAM L BOTELER JR.
510(k) history	5 submissions · 5 cleared · 1998-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981750/>. 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 29, 2026