

K981748 WIELISA ANCA SCREENING KIT TEST SYSTEMJul 22, 1998
65 days to decisionK981748 · 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	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

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