

**K974167 WIELISA PR-3 ANCA TEST SYSTEM**Feb 17, 1998  
104 days to decisionK974167 · Product code: **MOB** · Immunology  
Source: <https://www.510kdatabase.net/k974167/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Nov 5, 1997
Decision date	Feb 17, 1998
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wieslab AB</b>
Location	Frederick, MD, US
Contact	WILLIAM L BOTELER
510(k) history	5 submissions · 5 cleared · 1998-1998

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