

K974169 WIELISA ANTI-GBM TEST SYSTEMFeb 17, 1998
104 days to decisionK974169 · Product code: **DBL** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiple Autoantibodies, Indirect Immunofluorescent, Antigen, Control (DBL)
Date received	Nov 5, 1997
Decision date	Feb 17, 1998
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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