FDA 510(k) Premarket Notification

K981750 WIELISA ANTI-GBM, ANCA SCREENING KIT TEST SYSTEM

CLEARED

Jul 22, 1998
65 days to decision

K981750 · 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