

K051458 WIESLAB CAP PR-3 ANCANov 22, 2005
173 days to decisionK051458 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k051458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Jun 2, 2005
Decision date	Nov 22, 2005
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Eurodiagnostica
Location	Frederick, MD, US
Contact	WILLIAM L BOTELER JR.
510(k) history	3 submissions · 3 cleared · 2005-2005

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