

K965133 ANCA COMBI DIAGNOSTIC TEST KITMay 21, 1997
149 days to decisionK965133 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k965133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Dec 23, 1996
Decision date	May 21, 1997
Days to decision	149 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	The Binding Site, Ltd.
Location	Los Angeles, CA, US
Contact	JAY H GELLER
510(k) history	115 submissions · 115 cleared · 1988-2024

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