

K981030 BINDAZYME ANTI-MPO ENZYME IMMUNOASSAY KITJul 20, 1998
123 days to decisionK981030 · Product code: **MOB** · Immunology
Source: <https://www.510kdatabase.net/k981030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test System, Antineutrophil Cytoplasmic Antibodies (anca) (MOB)
Date received	Mar 19, 1998
Decision date	Jul 20, 1998
Days to decision	123 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981030/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026