

K983694 ANTICARDIOLIPIN IGM SCREEN EIA DIAGNOSTIC TEST KITFeb 5, 1999
107 days to decisionK983694 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k983694/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Oct 21, 1998
Decision date	Feb 5, 1999
Days to decision	107 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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