

K010148 ENA SCREEN EIA KITFeb 23, 2001
37 days to decisionK010148 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k010148/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jan 17, 2001
Decision date	Feb 23, 2001
Days to decision	37 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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