

**K010147 ENA EIA KIT**Mar 1, 2001  
43 days to decisionK010147 · Product code: **LLL** · Immunology  
Source: <https://www.510kdatabase.net/k010147/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jan 17, 2001
Decision date	Mar 1, 2001
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010147/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026