

**K004019 ANA EIA DIAGNOSTIC TEST KIT**Feb 15, 2001  
50 days to decisionK004019 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k004019/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Dec 27, 2000
Decision date	Feb 15, 2001
Days to decision	50 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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