

**K954700 ENZYME IMMUNOASSAY LUPUS SCREEN TEST KIT**Dec 15, 1995  
64 days to decisionK954700 · Product code: **LKJ** · Immunology  
Source: <https://www.510kdatabase.net/k954700/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Oct 12, 1995
Decision date	Dec 15, 1995
Days to decision	64 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Helix Diagnostics, Inc.</b>
Location	West Sacramento, CA, US
Contact	VIRGINIA L CAPPEL
510(k) history	15 submissions · 15 cleared · 1991-2000

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