

**K932419 ANTI-SS-B/LA ANTIBODY TEST**Aug 5, 1993  
79 days to decisionK932419 · Product code: **LLL** · Immunology  
Source: <https://www.510kdatabase.net/k932419/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	May 18, 1993
Decision date	Aug 5, 1993
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**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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