

**K913041 ANTI-DSDNA ANTIBODY TEST**Nov 5, 1991  
119 days to decisionK913041 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k913041/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jul 9, 1991
Decision date	Nov 5, 1991
Days to decision	119 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k913041/> 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 29, 2026