

**K960091 ENZYME IMMUNOASSAY ANTI-DOUBLE STRANDED  
DNA (DSDNA) TEST KIT**Mar 20, 1996  
69 days to decisionK960091 · Product code: LRM · Immunology  
Source: <https://www.510kdatabase.net/k960091/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Jan 11, 1996
Decision date	Mar 20, 1996
Days to decision	69 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/k960091/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 29, 2026