

**K931495 ENZYME IMMUNOASSAY ANTI-SS-A/RO ANTIBODY  
TEST KIT**Jul 16, 1993  
113 days to decisionK931495 · Product code: LLL · Immunology  
Source: <https://www.510kdatabase.net/k931495/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Mar 25, 1993
Decision date	Jul 16, 1993
Days to decision	113 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 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/k931495/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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