

**K951798 ENZYME IMMUNOASSAY ANTI-SCI-70 ANTIBODY  
TEST KIT**Jul 17, 1995  
90 days to decisionK951798 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k951798/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Apr 18, 1995
Decision date	Jul 17, 1995
Days to decision	90 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/k951798/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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