

**K951850 ENZYME IMMUNOASSAY ANTI-JO-1 ANTIBODY TEST
KIT**Jul 18, 1995
88 days to decisionK951850 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k951850/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Apr 21, 1995
Decision date	Jul 18, 1995
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Helix Diagnostics, Inc.
Location	West Sacramento, CA, US
Contact	VIRGINIA L CAPPEL
510(k) history	15 submissions · 15 cleared · 1991-2000

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