

**K940510 ENZYME IMMUNOASSAY ANTI-SM ANTIBODY TEST
KIT**Apr 20, 1994
75 days to decisionK940510 · Product code: **LKP** · Immunology
Source: <https://www.510kdatabase.net/k940510/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-sm Antibody, Antigen And Control (LKP)
Date received	Feb 4, 1994
Decision date	Apr 20, 1994
Days to decision	75 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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