

K940588 ENZYME IMMUNOASSAY ANTI-SM/RNP ANTIBODY TEST KITApr 20, 1994
71 days to decisionK940588 · Product code: **LKO** · Immunology
Source: <https://www.510kdatabase.net/k940588/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-rnp Antibody, Antigen And Control (LKO)
Date received	Feb 8, 1994
Decision date	Apr 20, 1994
Days to decision	71 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k940588/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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