

K954723 ENZYME IMMUNOASSAY ANA SCREENING TEST KITDec 15, 1995
63 days to decisionK954723 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k954723/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Antigen, Control (LKJ)
Date received	Oct 13, 1995
Decision date	Dec 15, 1995
Days to decision	63 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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