

K932850 ENZYME IMMUNOASSAY EXTRACTABLE NUCLEAR ANTIGENSep 24, 1993
106 days to decisionK932850 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k932850/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Jun 10, 1993
Decision date	Sep 24, 1993
Days to decision	106 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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