

**K980337 DIAMEDIX IMMUNOSIMPLICITY ANA (IS-ANA)
SCREEN TEST SYSTEM**May 12, 1998
104 days to decisionK980337 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k980337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jan 28, 1998
Decision date	May 12, 1998
Days to decision	104 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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