

K001900 ENZYME IMMUNOASSAY ANTI-SSDNA ANTIBODY TESTSep 11, 2000
81 days to decisionK001900 · Product code: **LRM** · Immunology
Source: <https://www.510kdatabase.net/k001900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Antibody (enzyme-labeled), Antigen, Control (LRM)
Date received	Jun 22, 2000
Decision date	Sep 11, 2000
Days to decision	81 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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