

**K914853 ANTINUCLEAR ANTIBODY (ANA) SCREENING TEST
KIT**Jan 15, 1992
79 days to decisionK914853 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k914853/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Oct 28, 1991
Decision date	Jan 15, 1992
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Reads Medical Products, Inc.
Location	Westminster, CO, US
Contact	DEBRA SONGER
510(k) history	2 submissions · 2 cleared · 1991-1992

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914853/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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