

K935416 RO EIA TEST KITMay 2, 1994
174 days to decisionK935416 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k935416/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Nov 9, 1993
Decision date	May 2, 1994
Days to decision	174 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	David A. Fuccillo, Ph.D.
Location	Washington, DC, US
Contact	PATRICIA B SHRADER
510(k) history	9 submissions · 9 cleared · 1994-1994

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