

K935413 ENA EIA TEST KITJun 2, 1994
205 days to decisionK935413 · Product code: LLL · Immunology
Source: <https://www.510kdatabase.net/k935413/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extractable Antinuclear Antibody, Antigen And Control (LLL)
Date received	Nov 9, 1993
Decision date	Jun 2, 1994
Days to decision	205 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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