

K964385 ELIAS ANA-HEP-2Mar 6, 1997
122 days to decisionK964385 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k964385/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Nov 4, 1996
Decision date	Mar 6, 1997
Days to decision	122 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Elias U.S.A., Inc.
Location	Osceola, WI, US
Contact	GOTTFRIED KELLERMANN, PH.D.
510(k) history	54 submissions · 54 cleared · 1992-1997

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