

K040291 EL-ANA PROFILES: ANTI-CHROMATINMar 11, 2004
34 days to decisionK040291 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k040291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Feb 6, 2004
Decision date	Mar 11, 2004
Days to decision	34 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Theratest Laboratories, Inc.
Location	Chicago, IL, US
Contact	MARIUS TEODORESCU
510(k) history	22 submissions · 22 cleared · 1991-2010

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