

K024031 THE THERATEST EL-ANA PROFILES: ANTI-CENTROMEREFeb 6, 2003
62 days to decisionK024031 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k024031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Dec 6, 2002
Decision date	Feb 6, 2003
Days to decision	62 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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