

**K950716 THERATEST EL-ANA PROFILES TEST SYSTEM**Sep 26, 1995  
238 days to decisionK950716 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k950716/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Jan 31, 1995
Decision date	Sep 26, 1995
Days to decision	238 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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