

**K955481 THERATEST KIT (MODIFICATION)**Mar 6, 1996  
112 days to decisionK955481 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k955481/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Nov 15, 1995
Decision date	Mar 6, 1996
Days to decision	112 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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