

**K952490 IMAGETITER INSTRUMENT, ANA TEST KIT &  
CALIBRATOR SERUM**Dec 15, 1995  
199 days to decisionK952490 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k952490/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	May 30, 1995
Decision date	Dec 15, 1995
Days to decision	199 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Image Analysis Systems</b>
Location	Elon College, NC, US
Contact	ROLLIN HEINZERLING
510(k) history	1 submissions · 1 cleared · 1995-1995

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