

**K954815 ORGENTEC ANTI-SS-A(RO) PIN IMMUNO ASSAY**Apr 18, 1996  
182 days to decisionK954815 · Product code: **LJM** · Immunology  
Source: <https://www.510kdatabase.net/k954815/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Oct 19, 1995
Decision date	Apr 18, 1996
Days to decision	182 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Orgentec</b>
Location	Windham, NH, US
Contact	RICHARD CONLEY
510(k) history	10 submissions · 10 cleared · 1995-1996

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