

K954832 ORGENTEC ANTI-SS-B(LA) PIN IMMUNO ASSAYApr 18, 1996
181 days to decisionK954832 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k954832/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	Oct 20, 1995
Decision date	Apr 18, 1996
Days to decision	181 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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