

K962054 ORGENTEC ANTI-SS-A(RO) ELISANov 15, 1996
171 days to decisionK962054 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k962054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody (enzyme-labeled), Antigen, Controls (LJM)
Date received	May 28, 1996
Decision date	Nov 15, 1996
Days to decision	171 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	American Laboratory Products Co., Ltd.
Location	Windham, NH, US
Contact	RICHARD CONLEY
510(k) history	27 submissions · 27 cleared · 1991-2002

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