

K962062 ORGENTEC ANTI-SM ELISANov 18, 1996
174 days to decisionK962062 · Product code: **LJM** · Immunology
Source: <https://www.510kdatabase.net/k962062/>**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 18, 1996
Days to decision	174 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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