

K955449 ORGENTEC ANTI-CARDIOLIPIN ELISA ASSAYMay 23, 1996
176 days to decisionK955449 · Product code: **MID** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Nov 29, 1995
Decision date	May 23, 1996
Days to decision	176 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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