FDA 510(k) Premarket Notification

K962926 ORGENTEC ANTI-CARDIOLIPIN SCREEN ELISA ASSAY

CLEARED

Oct 10, 1996
73 days to decision

K962926 · Product code: **MID** · Immunology
Source: https://www.510kdatabase.net/k962926/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jul 29, 1996
Decision date	Oct 10, 1996
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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