

K940403 ELIAS CARDIOLIPIN ANTIBODIESSep 20, 1994
236 days to decisionK940403 · Product code: **MID** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jan 27, 1994
Decision date	Sep 20, 1994
Days to decision	236 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Elias U.S.A., Inc.
Location	Osceola, WI, US
Contact	GOTTFRIED KELLERMANN, PH.D.
510(k) history	54 submissions · 54 cleared · 1992-1997

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