

K091845 CARDIOLIPIN AUTOANTIBODY IMMUNOLOGICAL TEST SYSTEMJun 7, 2010
350 days to decisionK091845 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k091845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jun 22, 2009
Decision date	Jun 7, 2010
Days to decision	350 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phadia US, Inc.
Location	Portae, MI, US
Contact	MARTIN ROBERT MANN
510(k) history	22 submissions · 21 cleared · 2006-2015

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