

K131821 ELIA(TM) CARDIOLIPIN IGA IMMUNOASSAYDec 23, 2013
186 days to decisionK131821 · Product code: **MID** · Immunology
Source: <https://www.510kdatabase.net/k131821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Anticardiolipin Immunological (MID)
Date received	Jun 20, 2013
Decision date	Dec 23, 2013
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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