

K122197 AUTOMATED IN VITRO QUANTITATIVE ASSAY FOR THE MEASUREMENT OF ALLERGEN SPECIFIC IGE ANTIBODIES

Aug 28, 2013
400 days to decision

K122197 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k122197/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Jul 24, 2012
Decision date	Aug 28, 2013
Days to decision	400 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k122197/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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