

K123275 IMMUNOCAP ALLERGEN i3, COMMON WASP VENOM (YELLOW JACKET), AND IMMUNOCAP ALLERGEN i4, PAPER WASP VENOMJun 28, 2013
252 days to decisionK123275 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k123275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Oct 19, 2012
Decision date	Jun 28, 2013
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Phadia AB
Location	Uppsala, SE
Contact	MARTIN MANN
Website	http://www.phadia.com
510(k) history	32 submissions · 32 cleared · 2007-2022

Phadia AB is a medical products company headquartered in Uppsala, Sweden. The company develops, manufactures, and markets blood test systems for clinical diagnosis and monitoring of allergy, asthma, and autoimmune diseases. Phadia AB received FDA 510(k) clearances from total submissions, with no denied submissions on record. The company's regulatory focus is entirely on Immunology devices. Clearances span from 2007 to 2022, establishing a consistent track record in immunoassay and allergen testing technologies. The company's cleared devices include immunoassay systems for...