

K163370 ImmunoCAP Allergen w1, Common ragweedMay 5, 2017
155 days to decisionK163370 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k163370/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Dec 1, 2016
Decision date	May 5, 2017
Days to decision	155 days
Third-party review	No
Summary / Statement	Summary
Other names	ImmunoCAP Specific IgE

APPLICANT

Company	Phadia AB
Location	Uppsala, SE
Contact	Carina Magnusson
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...