

**K151029 Phadia Prime**Jan 19, 2016  
277 days to decisionK151029 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k151029/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Radioallergosorbent (rast) Immunological (DHB)
Date received	Apr 17, 2015
Decision date	Jan 19, 2016
Days to decision	277 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Phadia AB</b>
Location	Uppsala, SE
Contact	Anna-Lisa Tiensuu
Website	<a href="http://www.phadia.com">http://www.phadia.com</a>
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...