

**K150854 ImmunoCAP Specific IgE**Dec 14, 2015  
258 days to decisionK150854 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k150854/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional   |
| Device classification | System, Test, Radioallergosorbent (rast) Immunological (DHB)  |
| Date received         | Mar 31, 2015  |
| Decision date         | Dec 14, 2015  |
| Days to decision      | 258 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |
| Other names           | ImmunoCAP Allergen f439, Hazelnut; ImmunoCAP Allergen f440, Hazelnut; ImmunoCAP Allergen f441, Walnut; ImmunoCAP Allergen f442, Walnut; ImmunoCAP Allergen f443, Cashew nut |

**APPLICANT**

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|----------------|---|
| Company        | <b>Phadia AB</b>  |
| Location       | Uppsala, SE   |
| Contact        | Carina Magnusson  |
| 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...

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