

K113841 IMMUNOCAP ALLERGEN COMPONENTS BUNDLESep 13, 2012
260 days to decisionK113841 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k113841/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Radioallergosorbent (rast) Immunological (DHB) |
| Date received | Dec 28, 2011 |
| Decision date | Sep 13, 2012 |
| Days to decision | 260 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 |

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