

**K111919 IMMUNOCAP SPECIFIC IGE ALLERGEN BUNDLE, 12
ALLERGEN COMPONENTS**Dec 22, 2011
168 days to decisionK111919 · Product code: **DHB** · Immunology
Source: <https://www.510kdatabase.net/k111919/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Radioallergosorbent (rast) Immunological (DHB) |
| Date received | Jul 7, 2011 |
| Decision date | Dec 22, 2011 |
| Days to decision | 168 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111919/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026