FDA 510(k) Premarket Notification

**CLEARED**

# K121156 AUTOMATED IN VITRO QUANTITATIVE ASSAY FOR THE MEASUREMENT OF ALLERGEN SPECIFIC IGE ANTIBODIES

Mar 13, 2013
331 days to decision

K121156 · Product code: **DHB** · Immunology
Source: https://www.510kdatabase.net/k121156/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Radioallergosorbent (rast) Immunological (DHB) |
| Date received | Apr 16, 2012 |
| Decision date | Mar 13, 2013 |
| Days to decision | 331 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Phadia AB** |
| Location | Uppsala, SE |
| Contact | MARTIN MANN |
| 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...