

**K972068 UNICAP SPECIFIC IGE FEIA ASSAY, LATEX  
ALLERGEN IMMUNOCAP K82**Jul 3, 1997  
30 days to decisionK972068 · Product code: **DHB** · Immunology  
Source: <https://www.510kdatabase.net/k972068/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                           |
| Submission type       | Traditional  |
| Device classification | System, Test, Radioallergosorbent (rast) Immunological (DHB) |
| Date received         | Jun 3, 1997  |
| Decision date         | Jul 3, 1997  |
| Days to decision      | 30 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Pharmacia, Inc.</b>                    |
| Location       | Mchenry, IL, US                           |
| Contact        | KAREN E MATIS                             |
| 510(k) history | 129 submissions · 126 cleared · 1976-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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