

K964152 UNICAP TOTAL IGE ASSAY/PHARMACIA TOTAL IGE CONTROLS LMHApr 23, 1997
189 days to decisionK964152 · Product code: **DGC** · Immunology
Source: <https://www.510kdatabase.net/k964152/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ige, Antigen, Antiserum, Control (DGC) |
| Date received | Oct 16, 1996 |
| Decision date | Apr 23, 1997 |
| Days to decision | 189 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964152/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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