

K821806 ORTHO CLG IMMUNE COMPLEX TEST SYSTEMJun 25, 1982
8 days to decisionK821806 · Product code: **DAK** · Immunology
Source: <https://www.510kdatabase.net/k821806/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Complement C1q, Antigen, Antiserum, Control (DAK) |
| Date received | Jun 17, 1982 |
| Decision date | Jun 25, 1982 |
| Days to decision | 8 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Ortho Diagnostic Systems, Inc. |
| Location | Carpinteria, CA, US |
| 510(k) history | 126 submissions · 126 cleared · 1981-1997 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k821806/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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