

**K931443 ORTHO*EPSTEIN-BARR VIRUS EA(D+R)-IGG
ANTIBODY ELIS**Nov 5, 1993
228 days to decisionK931443 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k931443/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Epstein-barr Virus, Other (LSE) |
| Date received | Mar 22, 1993 |
| Decision date | Nov 5, 1993 |
| Days to decision | 228 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k931443/> 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