

K914550 ANTINUCLEAR ANTIBODY IMMUNOGLOBULIN TEST SYSTEMFeb 11, 1992
123 days to decisionK914550 · Product code: **LKJ** · Immunology
Source: <https://www.510kdatabase.net/k914550/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antinuclear Antibody, Antigen, Control (LKJ) |
| Date received | Oct 11, 1991 |
| Decision date | Feb 11, 1992 |
| Days to decision | 123 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Diagnostic Resources, Inc. |
| Location | Walker, MI, US |
| Contact | BARBARA L WESTRICK |
| 510(k) history | 4 submissions · 4 cleared · 1981-1992 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k914550/> 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 June 30, 2026