

K911848 IMMUNOWELL RNP/SM ANTIBODY TESTMay 7, 1991
11 days to decisionK911848 · Product code: **LKP** · Immunology
Source: <https://www.510kdatabase.net/k911848/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Anti-sm Antibody, Antigen And Control (LKP) |
| Date received | Apr 26, 1991 |
| Decision date | May 7, 1991 |
| Days to decision | 11 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | General Biometrics, Inc. |
| Location | San Diego, CA, US |
| Contact | BRYAN L.KIEHL,PHD. |
| 510(k) history | 23 submissions · 23 cleared · 1989-1992 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911848/> 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