

**K911849 IMMUNOWELL SJOGRENS SYNDROME A
(RO)ANTIBODY TEST**May 7, 1991
11 days to decisionK911849 · Product code: **LKO** · Immunology
Source: <https://www.510kdatabase.net/k911849/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Anti-rnp Antibody, Antigen And Control (LKO) |
| 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 | L.KIEHL PHD. |
| 510(k) history | 23 submissions · 23 cleared · 1989-1992 |

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