

**K911850 IMMUNWELL SJOGREN`S SYNDROME B (LA)
ANTIBODY TEST**

May 7, 1991
11 days to decision

K911850 · Product code: **LKO** · Immunology
Source: <https://www.510kdatabase.net/k911850/>

SUBMISSION DETAILS

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 PH.D.
510(k) history	23 submissions · 23 cleared · 1989-1992

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Device record: <https://www.510kdatabase.net/k911850/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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