

**K911851 IMMUNOWELL SM ANTIBODY TEST**May 7, 1991  
11 days to decisionK911851 · Product code: **LKP** · Immunology  
Source: <https://www.510kdatabase.net/k911851/>**SUBMISSION DETAILS**

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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**

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Company	<b>General Biometrics, Inc.</b>
Location	San Diego, CA, US
Contact	BRYAN L.KIEHL,PH.D.
510(k) history	23 submissions · 23 cleared · 1989-1992

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