

K010301 IMMUNOWELL EA (D) IGG TESTJun 11, 2001
130 days to decisionK010301 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k010301/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Feb 1, 2001
Decision date	Jun 11, 2001
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Genbio
Location	San Diego, CA, US
Contact	Bryan Kiehl
510(k) history	10 submissions · 10 cleared · 1996-2001

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