

**K973940 IMMUNOWELL EBV VCA IGG TEST**Aug 10, 1998  
299 days to decisionK973940 · Product code: **LSE** · Microbiology  
Source: <https://www.510kdatabase.net/k973940/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Oct 15, 1997
Decision date	Aug 10, 1998
Days to decision	299 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973940/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026