

K973941 IMMUNOWELL EBNA IGG TESTAug 10, 1998
299 days to decisionK973941 · Product code: **LLM** · Microbiology
Source: <https://www.510kdatabase.net/k973941/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Antigen, Nuclear, Epstein-barr Virus (LLM)
Date received	Oct 15, 1997
Decision date	Aug 10, 1998
Days to decision	299 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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