

**K982350 EA-D IGM ELISA TEST SYSTEM**Nov 25, 1998  
142 days to decisionK982350 · Product code: **LSE** · Microbiology  
Source: <https://www.510kdatabase.net/k982350/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Epstein-barr Virus, Other (LSE)
Date received	Jul 6, 1998
Decision date	Nov 25, 1998
Days to decision	142 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Columbia Bioscience, Inc.</b>
Location	Frederick, MD, US
Contact	NORMAN JENKINS
510(k) history	13 submissions · 13 cleared · 1996-1999

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k982350/> 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