

K982348 EBNA-1 IGM ELISA TEST SYSTEMNov 25, 1998
142 days to decisionK982348 · Product code: **LSE** · Microbiology
Source: <https://www.510kdatabase.net/k982348/>**SUBMISSION DETAILS**

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

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

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