

K980598 EBNA-1 IGM ELISA TEST SYSTEMMay 1, 1998
73 days to decisionK980598 · Product code: **LLM** · Microbiology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Antigen, Nuclear, Epstein-barr Virus (LLM)
Date received	Feb 17, 1998
Decision date	May 1, 1998
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Clark Laboratories, Inc.
Location	Blairstown, NJ, US
Contact	WILLIAM L BOTELER, JR.
510(k) history	14 submissions · 14 cleared · 1992-1998

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